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Evaluation of the RCN's BIOTEK2021 programme

Final report

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Acronyms and abbreviations

BIA	User-driven Research-based Innovation (Brukerstyrt innovasjonsarena)
BIONÆR	Sustainable Innovation in Food and Bio-based Industries (Bærekraftig verdiskaping i mat- og biobaserte næringer)
BIOTEK2021	Biotechnology for Innovation (Bioteknologi for verdiskaping)
CRISPR/Cas9	Clustered Regularly Interspaced Short Palindromic Repeats / CRISPR- associated protein-9 nuclease
DLN	Digital Life Norway
DLNRS	Digital Life Norway Research School
DNA	Deoxyribonucleic acid
ELSA	Ethical, Legal and Social Aspects
EPSRC	Engineering and Physical Sciences Research Council, UK
ERA	European Research Area
ERA-CAPS	ERA-Net Coordinating Action in Plant Sciences
ERACoBioTech	ERA-Net Cofund on Biotechnologies
ERACoSysMed	ERA-Net Cofund "Collaboration on systems medicine funding to promote the implementation of systems biology approaches in clinical research and medical practice"
ERA-IB2	ERA-Net "Towards an ERA in Industrial Biotechnology"
ERA-MBT	Marine Biotechnology ERA-Net
ERA-NET	European Research Area Network
ERASysAPP	ERA-Net for Applied Systems Biology
ERASynBio	ERA-Net for the development and coordination of synthetic biology in Europe
EU	European Union
EUREKA	European network developing cooperation between SMEs, research centres and universities for industrial innovation
FHF	Norwegian Seafood Research Fund (Fiskeri - og havbruksnæringens forskningsfond)
FORNY2020	Programme for Commercialising R&D Results (Forskningsbasert nyskaping)
FRIPRO	Independent projects (Fri prosjektstøtte)
FUGE	Programme for Functional Genomics (Funksjonell genomforskning)
GLOBVAC	Global Health and Vaccination Research
GMO	Genetically modified organism
HAVBRUK	Large-scale Programme on Aquaculture Research (Stort program for havbruksforskning)

HSE	Health, Safety and Environment
Horizon 2020	EU Research and Innovation programme
IB	Industrial biotechnology
IDELAB	RCN's "Ideas laboratory" (Forskningsrådets idélab)
IKTPLUSS	Large-scale initiative on information technology and digital innovation (IKT og digital innovasjon)
IP	Intellectual Property
IPN	Innovation Projects for the Industrial Sector
MABIT	Programme for Marine Biotechnology (Marin bioteknologi)
NANO2021	Programme for Nanotechnology and Advanced Materials (Nanoteknologi og avanserte materialer)
NANOMAT	Programme for Nanotechnology and New Materials (Nanoteknologi og nye materialer)
NGO	Non-governmental organisation
NIFU	Nordic Institute for Studies in Innovation, Research and Education (Nordisk institutt for studier av innovasjon, forskning og utdannin)
NMBU	Norwegian University of Life Sciences (Norges miljø- og biovitenskapelige universitet)
NorZymeD	Enzyme Development for Norwegian Biomass
NTNU	Norwegian University of Science and Technology (Norges teknisk- naturvitenskapelige universitet)
OECD	Organisation for Economic Co-operation and Development
R&D	Research and Development
R&D&I	Research, Development and Innovation
PERMIDES	Personsalised Medicine Innovation through Digital Enterprise Solutions
POC	Point of Care
RCN	Research Council of Norway
RNA	Ribonucleic acid
RRI	Responsible Research and Innovation
SAMANSVAR	Programme for Responsible Innovation and Corporate Social Responsibility (Ansvarlig innovasjon og bedriftenes samfunnsansvar)
SFF	Centre of Excellence
SFI	Centre for Research-based Innovation
TERPENOSOME	Engineered compartments for monoterpenoid production using synthetic biology (An ERA-IB2 project)

TIPC	Transformative Innovation Policy Consortium
TRL	Technology Readiness Level
ТТО	Technology Transfer Office
UiB	University of Bergen
UiO	University of Oslo
UiT	Arctic University of Norway
UK	United Kingdom

Executive summary

This report presents the results of the evaluation of the ongoing large programme BIOTEK2021 run by the Research Council of Norway (RCN). The key purpose of the evaluation was to assess how BIOTEK2021 through its choice of priorities and instruments has worked so far in achieving its set objectives. The evaluation has been conducted by Faugert & Co Utvärdering AB (part of Technopolis Group) on behalf of the RCN's Division for Innovation and has also included an external Expert Group assigned by RCN. The work was performed in December 2016 – June 2017.

BIOTEK2021 - Biotechnology for Innovation programme

BIOTEK2021 is one of the RCN's large-scale Programmes. Originally planned for a period of ten years (2012-2021), it was recently converted into a rolling programme with no end date. The programme is a continuation of the programme Functional Genomics (FUGE), which was completed in 2011, and can be seen as integral in the implementation of the National Strategy for Biotechnology. BIOTEK2021 has a distinctly industry-oriented profile and its primary objective is to generate biotechnology that contributes to value creation and innovation in order to solve societal challenges in a responsible manner. Six sub-objectives are supporting this key objective and are focusing on Scientific Excellence, Differentiation, Innovation, Societal Challenges, Collaboration and Responsible Research and Innovation. The programme is targeting four thematic areas: 1) marine biotechnology; 2) biotechnology in agriculture; 3) medical biotechnology and 4) industrial biotechnology. Biotechnology R&D in Norway is also supported through several other thematic programmes as well as open competitive arenas, and to achieve desired effects, the BIOTEK2021 programme therefore coordinates its allocation of funding with these other existing funding opportunities.

During 2012-2016, twenty-one national programme calls as well as several other activities have taken place with the support of the programme and funding was allocated to large-scale, industry relevant researcher projects, optimisation projects, international cooperation projects through ERA-NETs and other strategic initiatives. Since 2012, RCN has allocated almost 1,026m NOK across 158 projects in the BIOTEK2021 programme. So far, almost 43% of the RCN funding has gone to researcher projects, including the large-scale, industry relevant researcher projects. The second largest category is optimisation projects with 33% of the funding and approximately 14% of the funding has been assigned to joint calls through different ERA-NETs. The reaming 10% of the funding went to other initiatives like the establishment of the Centre for Digital Life Norway and different events. Regarding the thematic areas, as of 2016 around 40% of the funding has been allocated to medical biotechnology, followed by 35% to marine biotechnology, 15% to industrial biotechnology and 7% to biotechnology in agriculture. The Norwegian University of Science and Technology, the University of Oslo, the Norwegian University of Life Sciences and the Oslo University Hospital dominate as recipients, having received almost 60% of the public funding so far.

Contribution to the Norwegian biotechnology field

In view of both the evaluation team and the Expert Group, it is still too early to evaluate the programme's contribution towards **scientific quality in Norwegian biotechnology research** in terms of such deliverables as publications, citations, patents, licensing agreements and established SMEs. The projects in the programme need more time to generate measurable results and impacts. However, there is a list of already achieved publication outputs, which is bound to increase even further and lead to the improvement of scientific excellence. In addition to the traditional bibliometric outputs, a strong presence of the Norwegian research teams in various European networks can also be treated as a contribution to the increasing scientific excellence in Norway. This seems to be working well, particularly due to the specific funding in BIOTEK2021 linked to the ERA-nets. Furthermore, a very large extent of the respondents believes that the programme contributes to an increase in the quality of biotechnological research in Norway as well as to an increase in cooperation among research environments related to biotechnology in Norway. Expected results from the researcher projects are

primarily increased competitiveness of their organisations, internationally and nationally scientific publication(s) in Open Access Journals, as well as scientific publications co-authored with research institutions outside of Norway and other Norwegian institutions. Expected results for the innovation/optimisation projects are primarily increased competitiveness of their organisations nationally and internationally as well as scientific publications co-authored with other Norwegian institutions.

Looking at the programme's contribution towards **societal and commercial innovation and value creation**, a focus on or at least a potential for innovation can be seen in all the activities of BIOTEK2021. Many of the projects can lead to increased industrial relevance of their research results, nationally and internationally commercialised results, ensure knowledge transfer and networking between the actors participating in the projects and within the biotechnology sector in general. At the same time, some believe that the programme setup does not always allow them to get needed help for the commercialisation aspects. A potential for societal impact is also present but is somewhat different between the types of funded projects. Some see larger increases in dissemination of results to actors outside the scientific community and attention to RRI aspects in the R&D activities of the project; others try to include the views from actors outside the scientific community. Overall, the perception is that the BIOTEK2021 programme as a whole creates meeting places for national dialogues in subjects relevant to biotechnology and contributes to an increase in research needed to address societal challenges.

The societal aspect is also seen in the focus on Responsible Research and Innovation, which is a strategic priority under the BIOTEK2021 programme. For the programme to contribute towards a more **societal technology development through continuous focus on responsible research and innovation (RRI)**, a framework for RRI was created. In the opinion of the Experts, the RCN and the evaluated programmes are in the forefront internationally when it comes to the implementation of the RRI perspective. The RRI framework and the Centre for Digital Life in Norway should act as an inspiration for other funding bodies across the world. However, the Experts stress that very often RRI is seen to be a loosely connected add-on to research programmes and might have also created polarisation, requiring further efforts in this area. While the RCN's RRI framework is based on an integration model of the science and society relation, criticisms are based on a separation model. Subscribing to either one of these models is ultimately a political question.

National and international alignment

A future decision on the revision of the programme should rest not only on the quantity and quality of the results but also on the programme's **alignment with national research strategies and international trends**. To assess that, it is important to look at the programme in a larger context. Since BIOTEK2021 represents only 15% of the RCN's funding for biotechnology R&D, several other thematic programmes are instrumental. BIOTEK2021 seems to function complementary to the open arenas (FRIPRO and BIA) and other thematic programmes; thus ensuring that all links in the value chain can be funded and there are no gaps in the development cycle from research to commercial products, goods and services. The programme also seems to be positioned well internationally.

In view of the external Experts, a differentiation approach taken by the programme in addressing the various needs and special features of each sector covered by the programme can be a good strategy. It makes sense when the point is to make sure that a small country has sufficient competence within all knowledge areas to utilise and benefit from the created knowledge and results. However, a sufficient knowledge level in research areas is not necessarily the same as being an innovation leader or even being technologically competitive at a global level. Often this needs investment at a different level at the same time, as it also demands an infrastructural match between business structure and research excellence in a country. Such an infrastructural match cannot simply be created over a short span of years even if the investment is massive. It is instead a long-term investment (decades) of a very large kind. Differentiation can therefore be a challenge for a small economy with limited resources, and it is a common theme among research policies to talk about prioritisation in order to strengthen areas of national or regional strength.

Additionality of BIOTEK2021

With any programme of the size and the purpose similar to BIOTEK2021, the questions which arise are: How crucial has the programme really been? Did it change the behaviour of the project participants? What would the biotechnology research landscape in Norway look like if it has not been for the programme? In other words, what any evaluation of this type should look into is the additionality of the programme.

There is no doubt that the BIOTEK2021 **programme has been important for the majority of the participants**. Many of the projects would not have happened or would have had to reduce either the scope, the duration or the composition of their project consortium if it had not been for the RCN funding. Although access to funding was an important reason for applying to the BIOTEK2021 programme, it was not the key one. Opportunities to establish or strengthen cooperation with a research institution, contribution to tacking societal changes, opportunities to increase value creation through the development of products, processes and services, and opportunities to establish or strengthen cooperation with companies were some of the motivating factors mentioned by the programme participants. The positive feedback about the programme was strengthened by a general **high level of satisfaction with the RCN's administration of the programme and available support**. Programme participants talk about flexibility and support during the project implementation, clarity of the call and requirements for project reporting. However, some signs of dissatisfaction have been noted with regards to the process of proposals assessment, selection, and feedback provided to the rejected applicants.

In summary, the evaluation team with the external Expert Group believe that the programme is on the right track. It has supported different types of projects in an active and flexible way targeting the achievement of the set objectives. The administration of the programme listened to its users, had an active internal evaluation process, showed flexibility and introduced novel funding opportunities during the period to further improve the chances of a successful programme.

Recommendations

To further improve the programme and ensure its further smooth development, the Experts and the evaluation team proposes a following set of recommendations:

- Continue the support of the optimisation projects and the ERA-NET theme
- Evaluate the compatibility of different tool (*"virkemiddelapparatet"*) to ensure that the new innovations can reach their commercial potential.
- Assess (in cooperation with the R&D institutions) various potential niches the biotechnology sector should seek to fill when making future programmes or developing products with commercial potential
- Consider focusing on the areas where Norway has a special advantage and strength and preferably a national business structure to better absorb the commercial potential of the programme
- Use more specialised calls to help address the question of prioritisation of some thematic subfields. However, ensure a good balance with more general calls
- Analyse a whole portfolio of biotech-funded projects at RCN together looking in particular into the rationale and motivation of industrial partners to join projects
- Include some tools (e.g. mentors, sign-posting) to improve the attention to commercialisation within the researcher projects
- Continue involving Technology Transfer Offices in running projects as a way to link innovation supporting actors more
- Evaluate ways (e.g. seminars) to help potential investors better understand the biotechnology field. This is best achieved in partnership with innovation supporting actors in Norway (e.g. Innovation Norway)

- Assess further development of the BIOTEK2021 funded projects and/or involved teams in securing EU funding
- Analyse national initiatives in other countries similar to the Digital Life Network in Norway, and evaluate the DLN initiative
- Spend efforts on information and communication activities in order to increase the awareness about DLN and its role
- Consider mobility of scientists within Norway in general and within a particular set-up such as the Centre for Digital Life as a way to promote the activities and purpose of DLN
- Consider alternating the level of funding allocated during the calls, e.g. by focusing the next calls on slightly smaller projects
- Consider introducing a two-stage application process for some types of projects
- Simplify the DLN application process and a procedure for including new partners and projects
- Review the feedback process and consider a more ambitious feedback routine
- Continue involving international evaluation committees in assessing some of the applications
- Consider a half-way evaluation of each project
- In case of joint calls with other funding organisations, assign all call and implementation related tasks just to one organisation

Sammendrag

Denne rapporten presenterer resultatene av evalueringen av Norges forskningsråds (NFR) pågående store program BIOTEK2021. Hovedmålet med evalueringen har vært å vurdere hvordan BIOTEK2021, gjennom valg av prioriteringer og instrumenter, har fungert til nå med tanke på programmets mål. Evalueringen er gjennomført av Faugert & Co Utvärdering AB (en del av Technopolis Group) på vegne av NFRs divisjonsstyre for innovasjon. Evalueringen har inkludert en ekstern ekspertgruppe nedsatt av NFR. Arbeidet ble utført i desember 2016–juni 2017.

BIOTEK2021 – Bioteknologi for verdiskaping

BIOTEK2021 er et av NFRs store programmer. Opprinnelig var programperioden planlagt å være ti år (2012–2021), men programmet ble nylig omgjort til et løpende program med åpen sluttdato. BIOTEK2021 er en videreføring av programmet Funksjonell genomforskning (FUGE), avsluttet i 2011, og kan ses som et ledd i implementeringen av regjeringens nasjonale strategi for bioteknologi. BIOTEK2021 har en særskilt industriorientert profil. Programmets hovedmål er å generere bioteknologi som bidrar til verdiskaping og innovasjon med tanke på å løse samfunnsutfordringer på en bærekraftig måte. Dette hovedmålet er støttet av seks delmål som fokuserer på vitenskapelig eksellens, differensiering, innovasjon, samfunnsutfordringer, samarbeid og ansvarlig forskning og innovasjon (RRI). Programmet retter seg mot fire tematiske områder: 1) marin bioteknologi. 2) bioteknologi i landbrukssektoren, 3) medisinsk bioteknologi og 4) industriell bioteknologi. Norsk bioteknologisk FoU blir også støttet i flere andre tematiske programmer, samt på åpne konkurransearenaer. For å oppnå ønskede effekter koordinerer derfor BIOTEK2021 tildelingen av midler med de øvrige støttetilbudene.

I perioden 2012–2016 har programmet støttet 21 nasjonale programutlysninger i tillegg til en rekke andre aktiviteter. Midlene har gått til storskala industrirelevante forskerprosjekter, optimaliseringsprosjekter, internasjonale samarbeidsprosjekter gjennom ERA-NET og andre strategiske tiltak. Siden 2012 har NFR utbetalt nesten 1,026 mNOK til 158 prosjekter i programmet. Så langt har nesten 43 prosent gått til forskerprosjekter, inkludert storskala industrirelevante forskerprosjekter, mens optimaliseringsprosjekter har fått 33 prosent av midlene. 14 prosent av finansieringen har gått til fellesutlysninger gjennom ulike ERA-NET, og de resterende 10 prosentene har gått til øvrige tiltak som etableringen av Senter for digitalt liv Norge og diverse arrangementer. Med tanke på de tematiske områdene har rundt 40 prosent av midlene gått til medisinsk bioteknologi, 35 prosent til marin bioteknologi, 15 prosent til industriell bioteknologi og 7 prosent til bioteknologi i landbruket (tall for 2016). Norges teknisk-naturvitenskapelige universitet, Universitetet i Oslo, Norges miljø- og biovitenskapelige universitet og Oslo universitetssykehus HF dominerer blant støttemottakerne med nesten 60 prosent av tildelt støtte så langt.

Bidrag til det norske bioteknologifeltet

Evalueringsteamet og ekspertgruppen er enige om at det er for tidlig å evaluere programmets bidrag til **vitenskapelig kvalitet i norsk bioteknologisk forskning** på bakgrunn av resultater som publisering, sitering, patenter, lisensavtaler og etablerte SMB-er. Prosjektene i programmet trenger mer tid til å generere målbare resultater og effekter. Det finnes imidlertid allerede en rekke oppnådde publiseringsresultater, som trolig bare vil øke i omfang og bidra til økt vitenskapelig eksellens. I tillegg til tradisjonelle bibliometriske resultater kan de norske forskningsgruppenes sterke tilstedeværelse i ulike europeiske nettverk ses som et bidrag til økende vitenskapelig eksellens i Norge. Dette ser ut til å fungere godt særlig på grunn av programmets finansiering i forbindelse med ERA-NET-ene. Videre tror en svært stor andel av respondentene at programmet bidrar til å øke kvaliteten på norsk bioteknologisk forskning samt til å øke samarbeidet mellom bioteknologiske forskningsmiljøer i Norge. Forventede resultater fra forskerprosjektene er hovedsakelig økt konkurranseevne for organisasjonene, vitenskapelig publisering i tidsskrifter med åpen tilgang nasjonalt og internasjonalt, samt vitenskapelig publisering i samarbeid med andre norske og utenlandske forskningsinstitusjoner.

Forventede resultater for innovasjons-/optimaliseringsprosjekter er i hovedsak styrket konkurranseevne for organisasjonene nasjonalt og internasjonalt, samt vitenskapelig publisering i samarbeid med andre norske institusjoner.

Ser man på programmets bidrag til **samfunnsmessig og kommersiell innovasjon og verdiskaping**, kan man se et fokus på, eller i det minste et potensial for, innovasjon innenfor alle programmets aktiviteter. Mange av prosjektene kan bidra til forskningsresultater med økt industriell relevans, nasjonalt og internasjonalt kommersialiserte resultater, sikring av kunnskapsoverføring og utviklede nettverk mellom de deltakende aktørene og innenfor bioteknologisektoren som helhet. Samtidig opplever enkelte at programmets utforming ikke alltid legger til rette for nødvendig bistand i forbindelse med kommersialiseringsaspekter. Det finnes også et potensial for samfunnsmessige effekter, men dette varierer noe mellom de ulike prosjekttypene. Enkelte ser en større økning i spredning av resultater til aktører utenfor det vitenskapelige fellesskapet, samt oppmerksomhet rundt RRI-spørsmål innenfor prosjektenes FoU-aktiviteter. Andre prøver å inkludere perspektivene til aktører utenfor det vitenskapelige fellesskapet. Inntrykket er generelt at BIOTEK2021 skaper møteplasser for nasjonal dialog innenfor temaer av relevans for bioteknologien, samt bidrar til en økende grad av forskning som er nødvendig for å møte samfunnsutfordringer.

Samfunnsaspektet er også til stede i fokuset på ansvarlig forskning og innovasjon, som er strategisk prioritert i programmet. For at BIOTEK2021 skal kunne bidra til en mer **samfunnsrettet teknologiutvikling gjennom stadig fokus på ansvarlig forskning og innovasjon (RRI)**, er det blitt utarbeidet et rammeverk for RRI. Ekspertenes vurdering er at NFR og programmet ligger i forkant internasjonalt når det kommer til implementering av RRI-perspektivet. Både rammeverket for RRI og Senter for digitalt liv Norge kan fungere som inspirasjonskilde for støtteorganer i resten av verden. Ekspertene understreker imidlertid at RRI svært ofte blir sett på som et løst tillegg til forskningsprogrammene og kan ha skapt polarisering. Det er behov for videre innsats på dette området. NFRs rammeverk for RRI baserer seg på en integrasjonsmodell for forholdet mellom vitenskap og samfunn. Kritiske røster støtter seg til en separasjonsmodell. Hvorvidt man støtter den ene eller den andre modellen er til syvende og sist et politisk spørsmål.

Nasjonal og internasjonal tilpasning

En beslutning om revisjon av programmet bør ikke bare basere seg på resultatenes mengde og kvalitet, men også på hvorvidt programmet er **i tråd med nasjonale forskningsstrategier og internasjonale trender**. For å avgjøre dette, er det viktig å se programmet i en større sammenheng. BIOTEK2021 står for kun 15 prosent av NFRs støtte til bioteknologisk FoU, og det er flere andre tematiske programmer inne i bildet. Programmet ser ut til å fungere som et komplement til de åpne arenaene (FRIPRO og BIA) samt til øvrige tematiske programmer. Dette sikrer at alle ledd i verdikjeden har muligheter for støtte, og at det ikke finnes noen hull i utviklingssyklusen fra forskning til kommersielle produkter, varer og tjenester. Programmet ser også ut til å stå i en god posisjon internasjonalt.

Ifølge den eksterne ekspertgruppen kan det være en god strategi å ha en differensiert tilnærming når det gjelder å adressere de ulike behovene og egenskapene til sektorene programmet dekker. Dette fremstår meningsfylt når poenget er å sørge for at et lite land har tilstrekkelig kompetanse innenfor alle kunnskapsområder når det gjelder å utnytte og dra fordeler av den utviklede kunnskapen og resultatene. Å opprettholde et tilstrekkelig kunnskapsnivå innenfor forskningsområdene er imidlertid ikke det samme som å være innovasjonsledende eller teknologisk konkurransedyktig i et globalt perspektiv. Ofte kreves det investeringer på andre nivåer samtidig ettersom det må være infrastrukturell match mellom forretningsstruktur og forskningseksellens i et land. En slik infrastrukturell match kan ikke opprettes i løpet av få år uansett hvor store investeringene er. I stedet kreves det en langsiktig investering (over flere tiår) av den svært store typen. Differensiering kan med andre ord være utfordrende for en liten økonomi med begrensede ressurser. Det er vanlig i forskningspolitikken å diskutere prioriteringer for å styrke nasjonalt eller regionalt sterke områder.

Programmets addisjonalitet

I forbindelse med alle programmer med tilsvarende størrelse og formål som BIOTEK2021, er det relevant å spørre: Hvor avgjørende har programmet egentlig vært? Har det endret adferden til prosjektdeltakerne? Hvordan ville det bioteknologiske forskningslandskapet i Norge sett ut hvis det ikke var for programmet? Med andre ord må enhver evaluering av denne typen se på programmets addisjonalitet.

Det er ingen tvil om at BIOTEK2021 **har vært viktig for de fleste av deltakerne**. Mange av prosjektene ville ikke ha blitt gjennomført, eller ville blitt gjennomført med redusert omfang, varighet eller sammensetning av prosjektkonsortium hvis det ikke hadde vært for finansieringen fra NFR. Imidlertid har ikke tilgangen på finansiering vært den viktigste motivasjonen til å søke om midler fra programmet. Muligheten til å etablere eller styrke samarbeid med forskningsinstitusjoner, bidra til å håndtere samfunnsmessige endringer, øke verdiskapingen gjennom utvikling av produkter, prosesser og tjenester, og til å etablere eller styrke samarbeid med selskaper, er noen av de motiverende faktorene programdeltakerne nevner. Den positive tilbakemeldingen forsterkes av en generelt **stor tilfredshet med NFRs administrering av programmet og tilbud om veiledning**. Programdeltakerne snakker om fleksibilitet og støtte i forbindelse med prosjektgjennomføringen, tydelige utlysninger og tydelige krav til prosjektrapportering. Vi har notert oss enkelte tegn på misnøye når det gjelder prosessen for vurdering av søknadene, samt utvalg, og når det gjelder tilbakemeldingen til søkere med avslag.

Oppsummert har evalueringsteamet og ekspertgruppen inntrykk av at BIOTEK2021 er på rett kurs. Programmet har støttet ulike typer prosjekter på en aktiv og fleksibel måte for å nå de oppsatte målene. Programadministrasjonen har lyttet til brukerne, hatt en aktiv intern evalueringsprosess, utvist fleksibilitet og introdusert nye finansieringsmuligheter i løpet av programperioden for å ytterligere øke sjansene for et vellykket program.

Anbefalinger

Når det gjelder å forbedre programmet ytterligere og sikre en fortsatt god utvikling, har ekspertene og evalueringsteamet følgende anbefalinger:

- Videreføre støtten til optimaliseringsprosjekter og ERA-NET.
- Evaluere kompatibiliteten i virkemiddelapparatet for å sørge for at nye innovasjoner kan nå sitt kommersielle potensial.
- Vurdere (i samarbeid med FoU-institusjonene) ulike potensielle nisjer som bioteknologisektoren burde prøve å dekke når man lager fremtidige programmer eller utvikler produkter med kommersielt potensial.
- Vurdere å fokusere på områdene hvor Norge har spesielle fortrinn og styrker, og gjerne også på en nasjonal forretningsstruktur for å bedre absorbere programmets kommersielle potensial.
- Ha mer spesialiserte utlysninger for å bidra til å adressere spørsmålet om prioritering av enkelte tematiske underområder. Dette må imidlertid balanseres godt med mer generelle utlysninger.
- Analysere hele porteføljen av finansierte biotek-prosjekter hos NFR og særlig undersøke hvordan industripartnere begrunner sin deltakelse i prosjektene.
- Inkludere enkelte verktøy (f.eks. mentorer eller "signposting") for å øke oppmerksomheten rundt kommersialisering i forskerprosjektene.
- Fortsette å involvere teknologioverføringskontorer (TTO-er) i pågående prosjekter som en måte å koble sammen innovasjonsstøttende aktører i større grad.
- Vurdere ulike tiltak (f.eks. seminarer) som kan hjelpe potensielle investorer med å forstå bioteknologifeltet bedre. Dette gjøres best i samarbeid med innovasjonsstøttende aktører i Norge (f.eks. Innovasjon Norge).

- Vurdere videreutvikling av prosjektene støttet av programmet og/eller involverte team når det gjelder å sikre EU-finansiering.
- Analysere nasjonale tiltak i andre land som ligner på det norske nettverket for digitalt liv, samt evaluere DLN-initiativet.
- Bruke krefter på informasjon og kommunikasjonsaktiviteter for å øke kjennskapen til DLN og DLNs rolle.
- Vurdere generell mobilitet for forskere innad i Norge samt innenfor en spesifikk ordning som Senter for digitalt liv for å fremme aktivitetene til og formålet med DLN.
- Vurdere å alternere støttenivået i utlysningene, f.eks. ved å fokusere på noe mindre prosjekter i de neste utlysningene.
- Vurdere å introdusere en to-trinns søkeprosess for enkelte prosjekttyper.
- Forenkle DLNs søkeprosess og en prosedyre for å inkludere nye partnere og prosjekter.
- Gjennomgå prosessen for tilbakemelding og vurdere en mer ambisiøs tilbakemeldingsrutine.
- Fortsette å involvere internasjonale evalueringskomitéer i vurderingen av enkelte søknader.
- Vurdere en halvtidsevaluering av hvert prosjekt.
- Legge alle oppgaver knyttet til utlysning og gjennomføring til kun én organisasjon ved felles utlysninger i samarbeid med andre støtteorganer.

1 Introduction

This report presents the results of the evaluation of the ongoing large programme BIOTEK2021 run by the Research Council of Norway (RCN). Faugert & Co Utvärdering AB (part of Technopolis Group) undertook this study for the RCN's Division for Innovation. The work was performed in December 2016-May 2017 with the support from the external expert group and delivered in June 2017.

1.1 The assignment

The key purpose of the evaluation was to assess how BIOTEK2021 through its choice of priorities and instruments has worked so far in achieving its set objectives. The following questions were raised for this evaluation:

- How have the priorities between different instruments of the programme given a project portfolio that contributes to the achievement of the programme's objectives? The particular focus in answering this question should be put on the contribution of the programme towards:
 - scientific quality in Norwegian research in the field;
 - societal and commercial innovation and value creation in the short- and long-term;
 - a more societal technology development through continuous focus on "responsible research and innovation" (RRI).
- How well does the programme meet national research policy priorities and national needs and trends?
- How well does the programme correspond with the international trends in the field?
- Are there international trends in the field that needs to be addressed in future priorities in the programme?

In addition, the evaluation was set to assess if the BIOTEK2021 programme's administration and available support forms (e.g. programme committees) have worked to achieve the goals of the programme.

As most of the projects are still running and it is too early to expect any significant results or impacts, the scientific, commercial or societal results and effects of individual projects funded by the programme has not been evaluated. Nor was it included in the assignment to evaluate the different support instruments used by RCN in the programme.

1.2 Evaluation steps

The evaluation incorporated various data collection and analysis techniques:

- Analysis of available background documentation and data related to the programme portfolio
- Exploratory interviews with members of the programme's steering committee and programme management
- Five case studies, including stakeholder interviews with individual programme participants
- Three web surveys bound for project managers, project partners and non-beneficiaries. The surveys were largely identical in design but the survey to project managers was more extensive. (See Appendices B and C for more details.)
- An external Expert Group assigned to the project by RCN brought their sectoral knowledge and international experience from academia and the private sector. Members of the Expert Group included:
 - Anders Lönneborg, Sensilect Consulting (chair)
 - Dr Päivi Teivainen-Lædre, Department Manager, Skretting Aquaculture Research Centre

- Professor Stefan Hohmann, Head of the Department of Biology and Biological Engineering, Chalmers University of Technology
- Professor Maja Horst, Head of the Department of Media, Cognition and Communication, University of Copenhagen
- Preliminary thoughts and findings were presented and discussed during the validation workshop at RCN on 12th May 2017. Representatives of various research organisations, technology transfer offices, companies as well as the Research Council who have not contributed to the evaluation during the earlier stages participated in this workshop

The evaluation that is summarised in this report was conducted during the period of December 2016–June 2017.

The evaluation team consisted of AnnaKarin Swenning, Anders Håkansson and Dr Jelena Angelis, of which the latter acted as project manager. The team was assisted by Dr Tomas Åström (methodological advice during the study), Ingvild Storsul Opdahl (background analysis), Pierre Lindman (technical assistance setting up and running an online survey) and Reda Nausėdaitė (analysis of the survey results).

The team thanks the contributors of this study for sparing their time and sharing their views about the BIOTEK2021 programme during the telephone discussions, online survey and the validation workshop. Special thanks go to the RCN team behind this evaluation for providing an access to the data, an assistance during the online survey and an ongoing support throughout the evaluation in answering various enquiries from the evaluation team and the external Expert Group.

1.3 Structure of the report

The report is structured as follows:

- After this first section, Section 2 presents international trends in the biotechnology field in order to set the context of the BIOTEK2021 programme not only nationally but also internationally
- Sections 3 describes the BIOTEK2021 programme, its sources, goals, structure and its funding instrument portfolio
- Section 4 brings forward the analysis of collected information around the evaluation questions assessing the programme's contribution to the improvement of scientific quality in the Norwegian biotechnology research, commercial innovation, contribution to the responsible research and innovation. It also includes a brief assessment of the programme's administration
- Finally, Section 5 summarises the conclusions and recommendations from the evaluation team and external Expert Group on how the programme can be further be shaped based on the feedback received from various key stakeholders and in line with the development of the biotechnology field nationally and internationally
- Appendix A contains the full Expert Group's report
- Appendix B contains the survey questionnaire answered by project managers
- Appendix C presents the full results of the online survey

2 International trends in biotechnology

This section presents the views of the external Expert Group on the international trends in biotechnology. Please see Introduction for more details about the Expert Group and Appendix A for the full Expert Report.

2.1 Trends in the biotechnology research and development

Biotechnology has for centuries been a cornerstone in the development of the modern society and it will most certainly continue to have a dominant influence on our society within the healthcare sector, in agriculture, forestry, aquaculture as well as in the marine sector and also for the development of new industrial processes and products from sustainable resources.

2.1.1 Human health

In most if not all high-income countries improving human health is a top priority. Not surprising that a significant amount of available resources is being dedicated to this area of biotechnology. This makes the field highly competitive and challenging. In the health care sector, biotechnology tools are and will be further applied in human genome research, development of new vaccines, understanding the biology and improving diagnosis and treatment of cancers, genetics, infectious and chronic diseases and malignancies. Biotechnology will also be central in developing and applying stem cell biology as well as regenerative medicine for clinical use and in developing bioengineering further with a focus on implants and devices.

Biotechnology can help improve human health in many ways. Human genome studies can be exploited to diagnose, prevent and cure disease, to better target treatments and avoid side-effects, and to identify novel biomarkers and therapeutic targets. Biotechnology approaches can also be used in the fight against antimicrobial resistance with studies of new antimicrobial treatments, vaccines and diagnostic tools. Multidisciplinary bio-design studies (e.g. bio instruments, devices, implants, bio-imaging, and sensors) that address key biomedical challenges as well as the application of metagenomics to human nutrition and disease/obesity are further important examples of biotechnological approaches to human health.

A trend in diagnosis is the development of Point of Care (POC) tests that enable a quick but still accurate enough answer at the patient's bedside, in the operating theatre or by the patient at his/her home. POC tests facilitate and improve an accurate diagnosis when a central clinical lab facility is not available.

2.1.2 Sustainable agriculture and forestry

The areas of breeding, reproduction technologies, nutrition and health care are important to enhance animal health and productivity.

The widespread worldwide use of antibiotics in livestock and poultry production has a serious effect on antimicrobial resistance and affects health not only of the animals but also of the people consuming animal products. Other examples where biotechnology will be useful concern breeding, animal food safety, metagenomics of the bacterial flora in the gastrointestinal track in livestock and poultry, nutrigenomics for optimisation of feed formulation, breeding for optimisation of feed utilisation, and utilisation of waste streams to create high-value proteins and fats.

Improved nutritional quality, and resistance against pests and diseases are central for the development of crops higher productivity. Breeding of crops which cope with the changing climate and the abiotic and biotic stress associated with it and the use of novel methods for breeding (i.e. genome editing) are other examples that require further attention. Developing crops to produce compounds for industrial purpose (i.e. modified starch, modified fatty acid composition, pharmaceutical compounds) should also be mentioned. Soil biology is an often-neglected field where biotechnology is likely to become even more important in the future. There are clear signs in modern industrial farming that normal bio-

diversity is reduced and many important organisms disappear from the soil. Metagenomics is an important tool to measure the diversity of organisms in the soil and will become a central tool in efforts to solve the challenging dilemma between maintaining a highly productive farming and at the same time maintaining a sustainable soil.

Forestry is an important source of raw material for different applications. There are features unique to forest trees that may be utilised for commercial purposes. Raw material from trees is already today used for new biomaterial and biofuel and will for sure be developed even further in the future. Cellulose, lignin, terpenes and other secondary compounds very difficult to synthesize from scratch are especially present in forest trees. Some of the special chemical compounds in forest trees are already purified and commercialised by Norwegian industry but the potential of forestry raw materials is presently not fully exploited. It is well known that cyclosporine was first obtained from a soil fungus found in Norway and there are likely also other useful compounds present in fungi, mosses, lichens and other organisms widespread in the Norwegian forests that are yet to be detected and utilised.

2.1.3 Sustainable aquaculture

Aquaculture is a large and growing business worldwide. This growth also means that the environmental impact of this business areas is also becoming more and more significant. In this perspective there should be an increased support to sustainable aquaculture biotechnology that can address the environmental concerns related to aquaculture and that at the same time can help enhance aquaculture productivity and contribute to food security not only in Norway but also internationally. Focus should be on research that supports improving feed and nutrition, aquatic health and breeding techniques.

Examples of project areas of interest include health of the aquaculture environment, prevention and cure of diseases, rapid diagnostic tools, breeding and genetics, antimicrobial resistance (new antimicrobial medicines, vaccines), mucosal immunity, studies on genome edited salmon (e.g. health issues, environmental questions and considerations about the consequences of accidental release of genetically modified fish into the ocean), technology and innovation facilitating increased production within biological and environmental constraints.

2.1.4 Bioprospecting marine resources

Large sectors of the marine ecosystems remain unexplored with respect to novel compounds and raw materials. Many countries have realised this and are devoting significant resources to explore the potential value these ecosystems may hold. Norway has access to many unique marine ecosystems and could utilise this great advantage to the best for the society. Examples include marine algae as a source for biofuels, different features of phytoplankton and extremophiles, discovery of novel microbial enzymes and biomaterials with special features. Value creation based on by-products, waste streams and effluents from fisheries and farming industry should also be explored in Norway as it is done in other countries with a significant marine business sector. The application of metagenomics of bioactive molecules and whole genome sequencing of native commercially important aquaculture species to generate novel and applicable knowledge is also an international trend to increase value of the products. Much remains to be discovered on the many unique features of the marine ecosystem and its diversity of life forms.

2.1.5 Nanobiotechnology

The combination of life science, engineering, and technology conducted at the nanoscale is gaining rapid attention and these multidisciplinary approaches for engaging in knowledge exchange towards targeted innovations is an international trend that Norway should follow closely. Nanotechnology is funded by the Research Council through a dedicated programme; however, when nanotechnology is now being applied in living organisms it is becoming more integrated with biotechnology. Nanotechnology is to be applied to new therapeutics and targeted drug delivery vehicles, when developing novel formulations to enhance the efficacy of existing drugs and to expand their therapeutic spectrum, for novel diagnostics and imaging tools aiding an early disease detection, for

sensors to detect chemicals, toxins and pathogens. Nanotechnology could potentially also be used to assess and evaluate impact of bio-plastics and for bio-based plastic production. There will also be a need to develop technologies to detect micro- and nanoparticles.

2.1.6 Industrial processes

Biotechnology has many applications to help improve different processes in the industry. It can greatly influence the development of more sustainable products and materials. Increased use of life-cycle analysis of products with a view on sustainable production is gaining increased attention worldwide and should also be stimulated in Norway. Biotechnology can further be applied to exploit the biosynthetic and bio catalytic capacities of the microbial communities to improve waste management, pollution mitigation, and for bioprocessing of indigestible biomass and production of biofuel from renewable resources. Metagenomics can help maintaining the fresh water and marine environments as a basis for a sustainable production and at the same time create an added value in the production.

2.2 ELSA and trends in Responsible Research and Innovation

Biotechnology has been the focus of public controversies for decades. This was the driver for a decision to include research on the Ethical, Legal and Social Aspects (ELSA) in the original Human Genome Project. Currently, these controversies seem to have somewhat "cooled off" compared to the heated global controversies seen around the birth of Dolly and the export of GMO to Europe in the 1990s. However, such controversies should not be viewed as a phenomenon that follow a linear development. Rather, they must be understood as the expression of deeply seated value-based political disagreements over the role of science in society. They are not simply disputes over the technology, but stem from the fact that while most people in western society perceives science to be a solution to societal problems, others see it as the cause of more problems than solutions.

Controversies about biotechnology has been one of the driving forces for the development of an agenda of research and political action on the improvement of the relationship between science and society which is now covering all scientific research. This agenda has been particularly strong in the EU. In the UK three cross-institutional centres for ELSA research in biotechnology were funded in the 1990's with a very large investment from the British research councils. Since then the UK has played a leading role in such research and in the development of the ELSA-programme into a multitude of research agendas in law, economics, social sciences and humanities.

In the EU during the last decade a focus of science in society has been developed into the "responsible research and innovation" (RRI) framework. The European Commission defines RRI as:

An approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation.¹

While this term has achieved a certain stable usage, it covers a loosely defined set of phenomena, and is being developed and implemented differently in different contexts. Generally, its most stable and entrenched usage can be found in policy circles within the EU while the concept has a more precarious life in other national contexts.

The concept of RRI has been particularly important in the Horizon2020 framework, where it has been the focus of specific actions as well as a cross-cutting issue to be addressed and promoted in many other framework objectives. What the experience from Horizon2020 demonstrates is that the interpretation of the idea of RRI is flexible. Impact studies have begun to emerge, but there is no overall knowledge of the more general effects of attention to RRI as a concept or a process in the Horizon2020 programme. Recently, policy documents from the EU have adopted a slightly changed use of language towards focusing more on the terms Open Science and Open Innovation as overall framework terms.

 $^{{}^{1}\,}https://ec.europa.eu/programmes/horizon 2020/en/h 2020-section/responsible-research-innovation$

Many countries, such as for instance Denmark, do not have a well-developed policy on RRI, although in some cases some of the content is covered through the use of other concepts, such as "Ethics" or "Scientific Social Responsibility". It is not uncommon for funding bodies to discuss how they can integrate forms of reflection and action aimed at achieving social desirability in the grant applications. Such considerations, however, also often lead to discussions about how to evaluate and assess such aspects in the peer review process.

Furthermore, there seems to be a general discrepancy between the uptake of the term RRI in some policy circles and the research community as a whole. In general, it would be most accurate to say that the awareness of RRI is uneven in scientific communities in the European countries. While some scientists have been engaged in discussions of social desirability of their research for decades, many other groups have not heard about this concept and are rather critical towards what they see as "more administrative demands" and grant application "box-ticking" which will at best have no real impact on science. It is not uncommon for scientists to comment that the entire RRI agenda seems very remote from what they do in their laboratories.

2.3 General trends

In addition to the activities in different areas of biotechnology mentioned above there are also trends that are more general and influencing all or most of these areas. Genome-wide analysis of DNA, RNA, protein and metabolites are already central in the field. Methodology is advancing to move omics analysis to the level of individual cells, tissues, whole organisms, populations and biological samples of soil, air, water and even the intestinal tract bio-flora. This type of analysis generates an immense amount of data that require both software, hardware and intellectual skills to handle and to extract useful information from. Bioinformatics and Systems Biology tool development and application is required for data analysis, interpretation as well as prediction and simulation of biological processes. A massive amount of data is already freely available where information has been extracted to only a limited extent. Even more data has likely been generated where availability is more restricted. Networks like Digital Life Norway (DLN) and collaborations like the EU funded PERMIDES are good examples of attempts to utilise this data for research, innovation and biotechnology based industry in Norway and in Europe.

Genome editing with the CRISPR/Cas9 technology has developed rapidly and enables the very precise genetic reprograming of many cell types. This technique has the potential to become an important tool for the treatment of many important human, livestock, poultry and fish diseases. CRISPR/Cas9 technology also has major potential in the breeding/engineering of animals, plants and microorganisms. However, the technology can also be seen to re-invigorate the standing controversies on biotechnology and its legitimacy might be a point for more heated public discussion in the future.

There is much focus today on environmental issues and an increased interest in finding ways to reduce climate gas emission, reduce and recirculate waste, and re-use man-made products. Biotechnology offers a potentially very important contribution in this process towards a more sustainable society. For example, already today biotechnology tools have contributed in many countries to improved fermentation processes and production of biofuel from organic waste. However, to further enhance these processes there is a need for a clearer national climate and environmental strategy and action plan.

3 Support to the Norwegian biotechnology field and the role of the BIOTEK2021 programme

3.1 Support to the biotechnology field in Norway

Biotechnology was one of three technology areas prioritised in the Government's white paper on research from 2005, *Commitment to Research*, and it was identified as a strategic area in the white paper from 2009, *Climate for Research*. However, support to the biotechnology field was provided even before 2005 and consequently, the Research Council of Norway has administered a variety of initiatives on biotechnology during the past twenty years. In December 2011, a National Strategy for Biotechnology was presented. The process of developing the strategy involved a large number of Norwegian R&D actors from different areas and a preparation of the state-of-the-art review of the field. In the strategy, biotechnology is viewed as a broad spectrum of enabling technologies that are vital to addressing societal challenges related to such areas as environment, energy, food production and health, and priority is given to initiatives in the interface between economic profitability, societal challenges and national advantages. Cross-sectorial cooperation involving new approaches to management and governance of research and innovation processes is required to be able to address societal challenges.²

To implement the strategy and further support the biotechnology research and development in Norway, the Research Council is supporting this scientific field through numerous programmes.

BIOTEK2021 is one of the Research Council's large-scale Programmes. Originally planned for a programme period of ten years (2012-2021), it was recently converted into a rolling programme with no end date. The programme is a continuation of the programme Functional Genomics (FUGE), which was completed in 2011. FUGE has been the Council's widest ranging strategic initiative with an overall budget of 1.6bn NOK. By contributing to better coordination and a more effective distribution of tasks at the national level, the programme has played a major role in developing the field of biotechnology research.³

Despite being a large-scale programme, BIOTEK2021 only disposes 15% of the Council's funding for biotechnology R&D. The Council has also allocated funding to biotechnology research under several other thematic programmes as well as open competitive arenas such as the funding scheme for independent projects FRIPRO and the Programme for User-driven Research-based Innovation (BIA). Apart from that, funding has been allocated to Centres of Excellence (SFF) and Centres for Research-based Innovation (SFI). Eight of twenty-one SFF centres as well as four of twenty-one SFI centres are in the field of biotechnology. Additionally, Norway participates in several joint international programmes in which biotechnology constitutes an important part, for example, the Eurostars Programme.⁴ Additionally, funding is also allocated directly from the government (to the institutions), Innovation Norway, and from industry-specific research funds as well as trade and industry. A recently published report from NIFU shows that in total 4.5bn NOK was spent on biotechnology R&D in Norway in 2015, which represents almost 8% of the total R&D in Norway in the same year.⁵

To achieve desired effects, the BIOTEK2021 programme therefore has to coordinate its allocation of funding with other existing funding opportunities for biotechnology projects. In accordance with the

² BIOTEK2012, State-of-the-art review of the field (in Norwegian): http://www.forskningsradet.no/publikasjoner. ISBN 978-82-12-02854-8

³ Work programme BIOTEK2021 (2012–2021): http://www.forskningsradet.no/publikasjoner. ISBN 978-82-12-03187-6

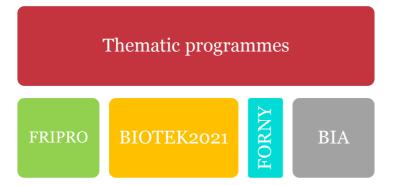
 $^{^{\}rm 4}$ Eurostars is a joint programme between EUREKA and the European Commission, co-funded from national budgets and by the European Union through Horizon 2020.

⁵ NIFU (2017). Bioteknologisk FoU 2015. Rapport 2017:5.

programme plan, BIOTEK2021 should focus on those areas where the use and development of biotechnology itself may make a difference.⁶

It is important that all links in the value chain can be funded and ensure that there are no gaps in the development cycle from research to commercial products, goods or services. Therefore, BIOTEK2021 (as well as other thematic programmes) functions complementary to open competitive arenas such as FRIPRO, BIA and FORNY2020 (the Programme for Commercialising R&D Results). Figure 1 shows the programme's position in relation to other funding instruments. The FRIPRO funding scheme for independent projects plays a part in the Research Council's overall strategic funding on biotechnology by financing basic research in the field. The BIA programme complements thematically oriented programmes by providing funding to companies and areas of specialisation that are not covered by one of the thematically oriented programmes. When it comes to the biotechnology, BIA has taken the responsibility for funding Innovation Projects for the Industrial Sector (IPN) and thus BIOTEK2021 in general does not fund IPN. FORNY2020 provides funding to proof-of-concept projects, which are not regarded as research.⁷

Figure 1 Position of BIOTEK2021 in relation to other RCN's funding instruments



Source: RCN.

3.2 The BIOTEK2021 programme

3.2.1 Rationale and priorities

The BIOTEK2021 programme can be seen as integral in the implementation of the National Strategy for Biotechnology. The programme uses the same definition of biotechnology as OECD and the National Strategy for Biotechnology, which is:

The application of science and technology to living organisms, as well as to parts, products and models thereof, to alter living and non-living materials for the production of knowledge, goods and services.

BIOTEK2021 has a distinctly industry-oriented profile. The programme focuses on developing biotechnological innovation and on the application of research results as a means of promoting value creation and industrial development related to solving major societal challenges in a responsible manner. This means that basic research within the field of biotechnology to a higher extent should be covered by FRIPRO, which is an open, national competitive arena that covers all fields of research. The emphasis is placed on the interdisciplinary work, which is necessary to achieve practical application of biotechnology. Particularly important is a link to other enabling technologies, such as nanotechnology and information technology. The development of a so-called knowledge-based bio-economy is also central to the programme. An important part of the programme activities is also to assess which international programmes and bilateral cooperation should be given priority and to what extent.

⁶ Work programme BIOTEK2021 (2012–2021): http://www.forskningsradet.no/publikasjoner. ISBN 978-82-12-03187-6

⁷ Work programme BIOTEK2021 (2012–2021): http://www.forskningsradet.no/publikasjoner. ISBN 978-82-12-03187-6

Actions in the European Research Area (ERA) are considered the most important in terms of international cooperation for the programme.⁸

The primary objective of BIOTEK2021 is to generate biotechnology that contributes to value creation and innovation in order to solve societal challenges in a responsible manner. In the programme plan, secondary objectives are also defined. The programme will:

- 1. Develop the generic elements within biotechnology, thus enabling Norwegian research groups in academia and industry to compete at an international top level (i.e. Scientific Excellence)
- 2. Address the various needs and special features of each sector in a manner that activates synergies and fosters cooperation (i.e. Differentiation)
- 3. Ensure that support is provided to areas in which biotechnology is essential for value creation and industrial development that benefits the society (i.e. Innovation)
- 4. Ensure the responsible development of technology that addresses global societal challenges in the areas of health and sustainable food and industrial production (i.e. Societal challenges, RRI)
- 5. Establish conditions that promote cooperation, constructive task distribution and highly focused research activity within Norwegian biotechnology research (i.e. Collaboration)
- 6. Communicate with specified target groups to ensure that biotechnology research and development are in line with the societal needs (i.e. RRI)

In line with the national strategy, the programme is focusing on four thematic areas of: 1) marine biotechnology; 2) biotechnology in agriculture; 3) medical biotechnology and 4) industrial biotechnology. The programme activities have to be adapted to the knowledge base found within each of the sectors?

- In the **marine sector**, the knowledge base for biotechnology must be expanded to ensure that Norwegian research groups remain at the international forefront of research. Priorities for this sector are also set in the national strategy for marine bioprospecting¹⁰.
- In the **agricultural sector**, the knowledge base will be expanded in selected areas through national and international cooperation.
- In the **medical sector**, the biotechnology knowledge base will be expanded while at the same time focus will be placed on better utilisation of existing research results. It will be taken into account that commercialisation of medical products and services is typically more time-consuming than in the other sectors, and priority will be given to industry-oriented research at R&D institutions.
- Regarding **industrial biotechnology**, a stronger knowledge base will be developed in selected areas through national and international cooperation. This sector is crucial for the ability to utilise R&D results in the three other sectors, and the programme's priorities for this sector will therefore be viewed in relation to the project portfolio in other sectors.

3.2.2 Programme management and execution

The BIOTEK2021 programme is funded by the Ministry of Research and Higher Education and the Ministry of Trade, Industry and Fisheries. The programme board is appointed by the Research Board for the Division for Innovation. At present, the board has nine members of which four represent the private sector (Table 1). At the Research Council, a programme administration under the direction of a programme coordinator is responsible for the day-to-day activities of the programme.

⁸ Work programme BIOTEK2021 (2012–2021): http://www.forskningsradet.no/publikasjoner. ISBN 978-82-12-03187-6

 ⁹ Work programme BIOTEK2021 (2012–2021): http://www.forskningsradet.no/publikasjoner. ISBN 978-82-12-03187-6
¹⁰ Marine bioprospecting – a source of new and sustainable wealth growth:

 $https://www.regjeringen.no/globalassets/upload/fkd/vedlegg/rapporter/2009/marine_bioprospecting_report.pdf$

Members	Organisation
Jostein Chr. Dalland (Styreleder)	Storebrand ASA
Stig Omholt	Norwegian University of Science and Technology
Jan Buch Andersen	Njorth Bio AS
Sigrid Fossheim	GE Healthcare
Anders Goksøyr	The University of Bergen
Elisabeth Kommisrud	Hedmark University of Applied Sciences/Sperm Vital AS
Karin Øyaas	Papir- og fiberinstituttet AS
Ellen-Marie Forsberg	Oslo and Akershus University College of Applied Sciences
Ragnhild A. Lothe	Oslo University Hospital

Table 1 Members of the BIOTEK 2021 programme board (since 2016)

Source: RCN.

3.2.3 Responsible Research and Innovation

During 2008, the Research Council of Norway launched an ELSA-programme for research into ethical, legal and social aspects of new technologies. The programme was focusing on biotechnology, nanotechnology and cognitive science. It can be seen as a continuation of the research activities that previously had been divided between the Ethics, Society and Biotechnology programme and the Large-scale Programmes FUGE (Functional Genomics) and NANOMAT (Nanotechnology and New Materials). The ELSA-programme collaborated closely with FUGE and NANOMAT, and from 2012 with BIOTEK2021 and NANO2021, in order to create coordinated and integrated initiatives on ELSA-related issues.¹¹ ELSA ended in 2014, and after that, RCN launched SAMANSVAR, a new programme with a focus on responsible innovation and Corporate Social Responsibility. This programme is built upon the experiences gained from the ELSA-programme.¹²

Over the years, the Research Council has developed its work on RRI in several ways. In 2015 RCN developed a common framework for RRI among the technology programs. This was inspired by the formal commitment to a framework for responsible innovation that was prepared in 2013 by the UK's Engineering and Physical Sciences Research Council (EPSRC). In parallel to developing the RRI framework, the Council has also developed a new overall strategy, Research for Innovation and Sustainability (2015–2020), which clearly stresses the role of research in society and the societal mission of the Research Council.¹³ International networking is also an important part of the Council's RRI-efforts. Now, the Council acts as a central actor in building a Transformative Innovation Policy Consortium (TIPC)¹⁴.

¹³ Research for Innovation and Sustainability (2015–2020):

¹¹ Work programme 2008 – 2014 for ELSA (http://www.forskningsradet.no/prognett-elsa/Forside/1224698247035)

¹² Work Programme 2015-2014. Programme on Responsible Innovation and Corporate Social Responsibility.

http://www.forskningsradet.no/en/Main_strategy_of_the_Research_Council/1185261825635

¹⁴ http://www.transformative-innovation-policy.net/

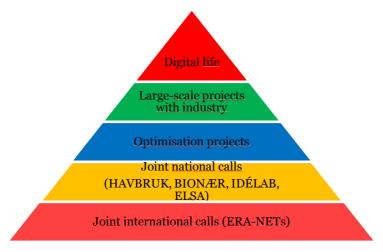
When it comes to BIOTEK2021, the National Strategy for Biotechnology 2012–2020 clearly states that the ethical, legal and other social aspects of the development of biotechnology need to be integrated more clearly in projects, programmes and initiatives that support biotechnological research and development activities.¹⁵ Together with other programmes (NANO2021, IKTPLUSS and SAMANSVAR) BIOTEK2021 has over the years initiated and supported different activities to promote and develop the work with Responsible Research and Innovation. In the different programme calls, RRI has been an important component that the projects needed to integrate in their work. For example, the optimisation projects must incorporate competence-building activities for key personnel regarding RRI. The Centre for Digital Life Norway, that received funding from BIOTEK2021 in 2015, also constitutes an important step in the work with RRI. All activities under the Digital Life initiative must be underpinned by the principle and practice of RRI. One example of the methods that have been developed and used to enhance learning and development regarding RRI is the so-called walkshop, where persons from the Centre for Digital Life, the Council and one of the large research projects within the Centre were walking while thinking about and discussing the future of biotechnology.

3.3 Programme portfolio

3.3.1 Project types

The Research Council of Norway is supporting different types of projects through BIOTEK2021 and creatively presents them in the "strategic pyramid". Figure 2 illustrates that the closer to the top of the pyramid, the more strategically designed is the activity to achieve the programme objectives.





Source: RCN.

One of the most common project types that is used is a **researcher project**, which is an R&D project designed to promote scientific renewal and development of disciplines and/or to generate new knowledge about issues relevant to society. However, by BIOTEK2021 the researcher projects have been developed into what has been called **Large-scale**, **industry relevant researcher projects** which focus on biotechnology as an enabling and multidisciplinary technology. The projects cover different aspects of the thematic areas and each project is funded with approximately 40m NOK. However, in comparison with NANO2021, the BIOTEK programme funds very few **Innovation Projects for the Industrial Sector** (IPN). This is a type of R&D project designed to lead to innovation (value-creating renewal) for the companies participating in the project. The reason for this difference is that BIOTEK2021 from the start has had a shared task with BIA to fund IPN projects in the biotechnology sector that are not covered by other innovation programmes (see Figure 1).

¹⁵ National Strategy for Biotechnology: http://www.regjeringen.no

Furthermore, the BIOTEK programme has developed a new project type, **optimisation projects**, which is only used in BIOTEK2021. This funding was introduced at the beginning of the programme and the purpose of the funding is to support research and development of biotechnology products, processes and services that have commercial potential, and where there is a need to develop and conceptualise the technology in order to adapt it to commercial use. Projects must be classified as TRL 2-5 on the EU's Technology Readiness Level (TRL) scale¹⁶. During 2013–2016, around 50 optimisation projects received funding with approximately 290m NOK.

The programme has also funded other types of initiatives, like **idea labs** – a method used to bring forward new and innovative ideas in the interfaces between different disciplines¹⁷ – and **strategic initiatives** as the Centre for Digital Life Norway. Moreover, the programme supports **European joint calls (ERA-NETs)**, and during the period allocated funding to international cooperation projects through the following ERA-NETs:

- Plant biotechnology (ERA-CAPS)
- Industrial biotechnology (ERA-IB2)
- Synthetic biotechnology (ERASynBio)
- Applied systems biology (ERASysAPP)
- Marine biotechnology (ERA-MBT)-Coordinator
- Systems medicine (ERACoSysMed)
- ERA-Net Cofund on Biotechnologies (ERACoBioTech)

Finally, the programme allocates funding to **events** in order to facilitate the efforts of Norwegian research institutions/companies in organising and hosting national or international conferences, workshops or seminars.

3.3.2 The evolution of programme calls and other activities during 2012–2016

During 2012-2016, twenty-one national programme calls as well as several other activities have taken place within the programme. In general, many of the calls had an innovative approach and the planning and implementation of these calls required extensive work.

In the first year of the programme, funding was allocated to five large-scale, industry relevant researcher projects. Funding was also allocated to optimisation projects, a new type of project that is used by the programme, and to joint calls between BIOTEK2021 and the thematic programmes HAVBRUK¹⁸ respectively BIONAER¹⁹. Apart from that, funding was allocated to joint calls with three different ERA-NETs. In total approximately 330m NOK was distributed in 2012.²⁰

In 2013 approximately 168m NOK was granted to new projects, for example optimisation projects and IPN-projects. Funding was also allocated to joint calls with different ERA-NETs, and to the Council's first Idea Lab. During this year, the Council started to define a strategic and visionary initiative, Digital

¹⁶ Technology Readiness Levels (TRLs) are indicators of the maturity level of particular technologies. TRL 1 – basic principles observed; **TRL 2 – technology concept formulated; TRL 3 – experimental proof of concept; TRL 4 – technology validated in lab; TRL 5 – technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies); TRL 6 – technology demonstrated in relevant environment (industrially relevant environment; TRL 8 – system complete and qualified; and TRL 9 – actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space).**

https://ec.europa.eu/research/participants/portal/desktop/en/support/faqs/faq-2890.html

¹⁷ *Idea Lab* is a method used by the Research Council to bring forward new and innovative ideas in the interfaces between different disciplines (http://www.forskningsradet.no/prognett-lab/Hva_er_en_idelab/1253988810676).

 $^{^{18}}$ HAVBRUK is a large-scale programme on Aquaculture Research (http://www.forskningsradet.no/prognett-havbruk/Home_page/1226994216880).

¹⁹ BIONAER is a research programme on Sustainable Innovation in Food and Bio-based Industries (http://www.forskningsradet.no/prognett-bionaer/Home_page/1253971968569).

 $^{^{\}scriptscriptstyle 20}$ Annual report 2012 for BIOTEK2021

life-convergence for innovation, which would focus on facilitating "a major shift towards a concerted use of conceptual, methodological and technological elements from the life sciences, mathematical sciences and engineering throughout the whole biotechnological innovation process".²¹ A foundation for ELSA- and RRI-related activities for the first part of the programme period was also established.²²

In 2014 approximately 120m NOK was granted to new projects. Both optimisation projects and IPNprojects received funding, and joint calls were conducted with other programmes such as HAVBRUK, NANO2021 and ELSA. Funding was also allocated to joint calls with different ERA-NETs, and the process of defining the strategic initiative Digital life-convergence for innovation resulted in a call to establish a Centre for Digital Life.²³ In September 2015, the Research Council granted 250m NOK for the establishment of a Centre for Digital Life as well as to six large research projects with topics spanning from aquaculture to brain research. The projects will be carried out under the auspices of the Centre. Linked to this initiative, funding was also allocated to the establishment of a national graduate school, since development of new skills and capacities is important in strengthening the innovation culture in the research area.

Other activities conducted during 2015 included a pilot cooperation with the Norwegian Cancer Society regarding funding of innovative cancer treatment and diagnostics. Almost 50m NOK was allocated to the projects. Furthermore, optimisation projects and joint calls with ERA-NETs received funding. The Council has also started to develop a strategic view on how BIOTEK2021 should interact with various parts of the EU Research and Innovation programme Horizon 2020. For that purpose, funding was made available to stakeholders who wish to influence the programme development in Horizon 2020. So far, the interest from the stakeholders for this funding has been absent and the call announcement was discontinued. Regarding the RRI activities, BIOTEK2021 has been working together with the programmes IKTPLUSS²⁴, NANO2021 and SAMANSVAR²⁵ on the establishment of a common framework for RRI. During 2015 it was also decided that BIOTEK2021 should be converted into a rolling programme with no end date. A new programme board was appointed and the first meeting was held in December 2015.²⁶

In 2016 funding was allocated to optimisation projects. During this year, a call for additional researcher projects associated with the Centre for Digital Life was launched.

3.3.3 Project portfolio²⁷

Since 2012, RCN has allocated almost 1026m NOK across 158 projects in the BIOTEK2021 programme. Additionally, 11 projects were also transferred from FUGE to BIOTEK2021. Figure 3 exhibits the distribution of the budget allocated to funded projects for 2012–2021. As the programme has been running for five years and has no end date (i.e. it is an ongoing programme), the presented numbers will increase during the course of the programme as new projects get funded. Taking the projects' co-funding into account, the programme peaked in 2017 with almost 350m NOK in project funding.

²⁶ Annual report 2015 for BIOTEK2021

²¹ Strategic Initiative "Digital Life – Convergence for Innovation", <u>strategic document</u>

²² Annual report 2013 for BIOTEK2021

²³ Annual report 2014 for BIOTEK2021

 $^{^{24}}$ IKTPLUSS is a large-scale initiative on information technology and digital innovation (http://www.forskningsradet.no/prognett-iktpluss/Programme_description/1254002053610).

 $^{^{25}}$ SAMANSVAR is a programme for research on responsible innovation and Corporate Social Responsibility (http://www.forskningsradet.no/prognett-samansvar/Home_page/1254002580879).

²⁷ For reasons of consequence, calculations on the RCN's project funding and related co-funding is based on the budget in the initial contract for all projects.

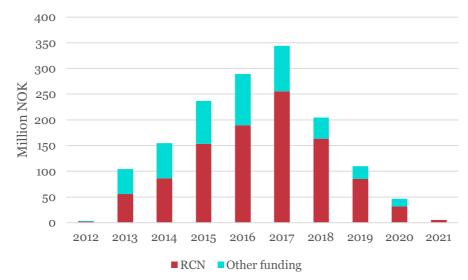
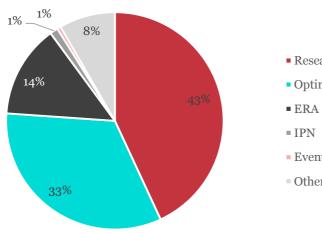


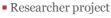
Figure 3 Granted funding and co-funding per year

Source: Technopolis' analysis of RCN data.

Figure 4 shows that almost 43% of the RCN funding was allocated to researcher projects; 20 projects received approximately 440m NOK. Five of these projects are the large-scale, industry relevant researcher projects, which got almost 40m NOK each. The second largest category is optimisation projects with 33% of the funding from RCN; 52 optimisation projects received 338m NOK. Approximately 14% of the funding was allocated to joint calls through different ERA-NETs and 8% of the funding went to other initiatives like the establishment of the Centre for Digital Life Norway. So far, only three IPN projects received funding with approximately 12m NOK. Finally, when it comes to events, 44 activities obtained around 5m NOK.



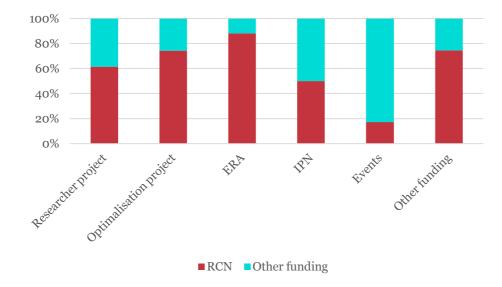




- Optimalisation project
- Events
- Other funding

Source: Technopolis' analysis of RCN data.

Figure 5 shows granted funding and co-funding per project type. IPN-projects normally demand at least 50% co-funding from participating organisations, and so far, the IPN-projects have had an average 50% co-funding. Researcher projects allow for full funding from RCN, but the average share of co-funding in these projects is 38%.

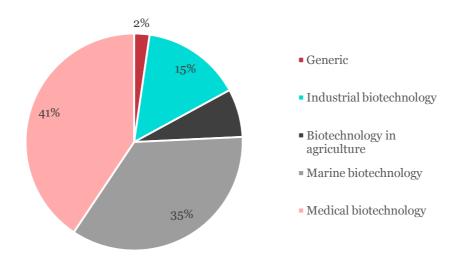




Source: Technopolis' analysis of RCN data.

All funded projects have been mapped by RCN based on which of the thematic priority areas they are addressing. The share of funding per thematic area for 2016 has been analysed (see Figure 6). A breakdown of the allocation of resources reveals that around 40% is bound for medical biotechnology, followed by marine biotechnology at 35%. Almost 15% is allocated to industrial biotechnology and 7% to biotechnology in agriculture.



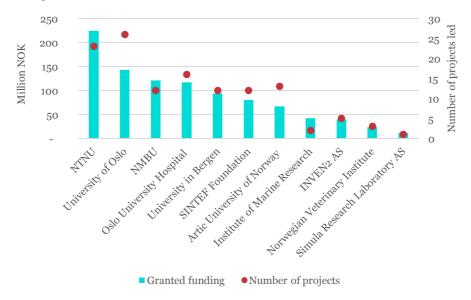


Source: RCN.

Figure 7 shows the participation of R&D performers, companies and other organisations in BIOTEK2021, both in funding amount received and number of projects led. Organisations which got less than 10m NOK are not included in the figure. However, the analysis contains some caveats. This figure takes into account only those organisations which have actually received the RCN funding and does not take projects' internal transferals into account. The figure also shows how many projects each organisation is leading, but not how many project these organisations participated as partners. Because of how the RCN data is organised, it was not feasible to perform this kind of analysis within the timeframe of this evaluation.

With those limitations in mind the Norwegian University of Science and Technology (NTNU) has so far received 224m NOK and coordinated 23 projects funded under the programme. The University of Oslo (UiO) joins NTNU as the second leading organisation in the programme with 143m NOK granted and 26 project ownerships. The Norwegian University of Life Sciences (NMBU) and the Oslo University Hospital were granted 120m NOK and 116m NOK respectively. Following that, the University of Bergen (UiB), SINTEF Foundation and the Arctic University of Norway (UiT) received 93m NOK, 80m NOK and 67m NOK respectively. The rest of the organisations have one or up to three project ownerships, and got less than 40m NOK each in the BIOTEK2021 funding.

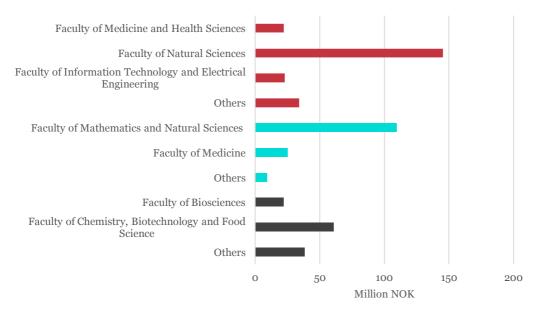
Figure 7 Granted funding (more than NOK10m) and number of projects led by R&D performers, companies and other organisations



Source: Technopolis' analysis of RCN data. Note: turquoise bars and left axis – granted funding; red circles and right axis – number of projects.

A breakdown of funding per faculty at the three largest beneficiaries, NTNU, UiO and NBMU, reveals that the faculties of natural sciences in NTNU and UiO, and the Faculty of Chemistry, Biotechnology and Food Science in NBMU, are the primary recipients, see Figure 8.

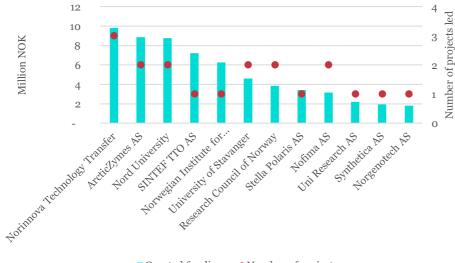
Figure 8 Breakdown of granted funding (more than NOK10m) per faculty at NTNU (red bars), UiO (blue bars) and NMBU (black bars)



Source: Technopolis' analysis of RCN data. Note: Category 'Others' refers to all other funding allocated either to a given university but where it was not possible to say which department exactly.

Figure 9 shows the participation of R&D performers, companies and other organisations, which have been granted funding between 1m and 10m NOK.

Figure 9 Granted funding (between 1 and 10m NOK) and number of projects led by R&D performers, companies and other organisations



Granted funding •Number of projects

Source: Technopolis' analysis of RCN data. Note: turquoise bars and left axis – granted funding; red circles and right axis – number of projects.

4 Contribution of the BIOTEK2021 programme

4.1 Achieved results

Although assessment of the results achieved through the BIOTEK2021 projects was not the purpose of this evaluation (especially due to the fact that most of the projects are still ongoing), it is nevertheless useful to have a brief glimpse into the results in order to understand what individual projects funded through the programme are delivering.

RCN captures some result indicators in the programme's annual reports, which are based on the reports from the funded projects. A compilation of these is presented in Table 2.

The programme accounts for a steadily growing number of scientific publications (especially journal articles) and an impressive collection of other 'grey' literature (technical reports, popular science, media covering). The number of technical reports is especially impressive and increased a lot in 2014–2015 from 80 in 2013 to 146 (in 2014) and 201 (in 2015).

Table 2 Compilation of reported results achieved by projects in BIOTEK2021 (and to some extent by projects that were transferred from FUGE) during 2012–2015

	2012	2013	2014	2015
Scientific publication				
Journal articles	9	33	49	73
Articles in anthology	1	3	9	27
Monographs	1	0	2	2
Other publications				
Technical reports	26	80	146	201
Popular science	4	12	9	31
Media covering	5	21	21	85
Innovation indicators				
New or improved methods, models, prototypes	0	4	7	13
New or improved products	2	4	2	25
New or improved processes	1	0	2	1
New or improved services	0	6	0	0
Patent applications	1	4	13	13
Licence agreements	0	1	0	0
New companies as a result of the project	0	0	2	2
New business areas in the existing companies	0	0	0	3
Introduction of new/improved methods/technologies in participating companies	о	0	3	4
Introduction of new/improved methods/technologies in other companies	о	0	0	1
Introduction of new/improved working processes/business areas in participating companies	0	0	0	1

Source: BIOTEK2021 Annual Reports.

The innovation indicators, such as new or improved products and methods, models and prototypes, have substantially increased in 2015. And the number of patent applications jumped between 2013 and 2014 and stayed on the same level (13 applications/year) in 2015. The weakest performance so far is observed in the improvement of processes and services, with a very few processes and services developed and introduced in companies.

In addition to the innovation indicators reported in annual reports, some of the respondents to the survey conducted during this evaluation provided examples of specific technologies and research they were working on which was made possible with the help of the BIOTEK2021 funding. These are examples of innovations with potential application on an international scale which could greatly increase the visibility of the Norwegian R&D.

Achievement of many of the listed results is stimulated through the involvement and active participation in various networks. There seems to be a resounding consensus among participants in the programme that their projects indeed yield increased networking and knowledge transfer between actors in the projects. On a grander scale the development of research networks was also suggested as an outcome facilitated by the programme. Although some participants noted that the development of networks may not necessarily has been part of their agenda as such but rather an action necessary to take in order to qualify for research funding, there are many examples proving a long-term lasting effect of networks.

The topic of networks (and especially international networks) is of particular relevance and interest to the researchers taking part in the ERA-NET projects. One of the case studies analysed during this evaluation serves as a good example of such networks and their benefits.

TERPENOSOME (Engineered compartments for monoterpenoid production using synthetic biology)

TERPENOSOME is the transnational research project which was funded as part of the ERA-IB2 network. The project runs from July 2014 until June 2017. The goal of the ERA-IB2 network is to reduce fragmentation of national research efforts and achieve sufficient critical mass and better use of scarce resources in the field of Industrial Biotechnology (IB). The network started in 2006 as ERA-IB within the ERA-NET "Towards an ERA in Industrial Biotechnology" funded from the European Commission's Sixth Framework Programme for Research and Technological Development (FP6). After its 5-year tenure, further funding was secured from the FP7. Projects are selected and funded through joint calls. TERPENOSOME was part of the 4th call. In total 45 transnational project applications were submitted then but only nine projects were funded with the total C14m. This call was for the first time organised in collaboration with EuroTransBio (ETB), a network of ten research programme funding and/or management organisations with a focus on industrial research especially SMEs. It was also the first call where the Research Council of Norway was one of the participating funding institutions.

The project involves five partners from three countries, each with distinguished academic and/or commercial background in synthetic biology for microbial production of small bioactive molecules. Professor E. Takano from the University of Manchester (UK), who put together an idea for the project, coordinates the project. Two other academic partners are Georg-August-Universität Göttingen from Germany and the Norwegian University of Science and Technology. In addition, involvement of two commercial partners from Germany – Aroma Chemical Services International GmbH and Life Technologies – increases the potential for translation of the academic findings to new commercial products, processes and services.

This consortium was newly formed and did not exist prior to the call. That was a purely new project (i.e. not shaped for this particular call) but was based on other research performed at Manchester. The Norwegian partner did not get any funding from FUGE (predecessor of BIOTEK2021). However, some of the partners had or have joint funding/collaborations or publications. For example, Professor Takano knew the research and competences at the Norwegian University of

Science and Technology, and invited them to join the consortium.

This international project made the Norwegian partner more and more internationally focused realising all the benefits of the international academic society. The mobility was not that high in the past but the situation has improved and is clearly leading to some tangible effects. For example, the project led to the attraction of post-docs from abroad, e.g. only last year three post-docs from the Czech Republic, Japan and India were employed. Many Erasmus+ students (c. 5-6 per year) get involved in the research group and spend 4-6 months in the lab; and guest researchers from Argentina and Brazil got attracted by the research being developed in the group.

In addition – as commented by the external Expert Group – it is obvious from the annual reports and other documents that there has been a number of events and other communication activities, but the expert team did not have particular information about the impact of these activities. Such impact is also very difficult to assess. It looks as though such efforts are in line with what has been done internationally.

Results delivered by the projects are fundamental in trying to answer the first evaluation question on the contribution of the portfolio of funded projects towards the achievement of the BIOTEK2021 programme's objectives. Such contribution can take different forms. This evaluation has specifically asked for the programme's contribution towards scientific quality in Norwegian biotechnology research; societal and commercial innovation and value creation in the short- and long-term; and a more societal technology development through continuous focus on Responsible Research and Innovation. An evidence of these various contributions is presented further in this section.

4.2 Programme's contribution to scientific quality

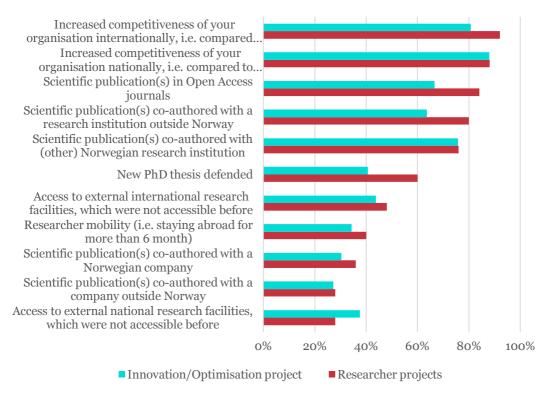
When examining results and contribution it is important to keep in mind that the project portfolio is rather heterogeneous, ranging from relatively small and short projects to some quite large multidisciplinary projects engaging research and other organisations nationwide. Figure 10 shows a sample of the results most frequently expected to be achieved according to the surveyed project participants. The full set of results can be found in Appendix C.

For researcher project respondents the most likely outcomes were increased competitiveness of their organisation nationally (92% agreed), increased competitiveness of their organisation nationally (88% agreed) and scientific publication(s) in Open Access Journals (84% agreed). In case of innovation/optimisation projects the results for competitiveness switched places: increased competitiveness of their organisation nationally was named first (88% agreed) while increased competitiveness of their organisation internationally (81% agreed) came second. Scientific publication co-authored with other Norwegian institutions came in 3rd place for innovation/optimisation projects (76% agreed) and 5th for researcher projects (76% agreed). Alternatively, researcher project respondents ranked scientific publication co-authored with research institutions outside of Norway higher at 4th place (80% agreed while only 64% of innovation/optimisation projects look more interested and focused on international dimension while innovation/optimisation projects more so on the national dimension when carrying out their projects.

Regarding the question about the BIOTEK2021's contribution to the scientific quality, almost all (91%) of the respondents for the researcher project respondents and 88% of the respondents for the innovation/optimisation projects agree or strongly agree with the statement that the programme contributes to an increase in the quality of biotechnological research in Norway. Regarding cooperation, 88% of the respondents for the respondents for the respondents and 79% of the respondents for the innovation/optimisation projects also agree or strongly agree with the statement that the programme contributes to an increase in cooperation among research environments related to biotechnology in Norway. However, the lowest scores by both researcher and innovation/optimisation project respondents were given to an increase of research mobility between research environments

related to biotechnology in Norway (65% for researcher projects and 56% for innovation/optimisation projects).

Figure 10 Respondents' view on what scientific / academic results they expect their projects to achieve



Source: Online survey. Note: Share of respondents who answered "Agree" and "Strongly agree".

Although it is not possible to assess the degree of excellence based on bibliometric or other tools since most of the funded projects are still running, the external Expert Group which contributed to this evaluation also notes that the survey demonstrates that a majority of respondents expect the project to lead to improvement of scientific excellence. An indicator of scientific excellence is how well Norwegian research teams are represented in European networks. This seems to be working well, particularly due to the specific funding in BIOTEK2021 linked to the ERA-NET, but it is not clear whether funded research teams as a continuation of their projects also have received EU-funding.

The external Expert Group which took part in this evaluation note that in the explicit goal to foster excellence and innovation, the decision was made to setup the Centre for Digital Life Norway and to allocate a third of the funding for this initiative. The strategic vision paper for this ambitious initiative describes how it should be at the forefront of interdisciplinary research in biotechnology. The objective is to create value through transdisciplinary research to *"support the integrated development of biotechnology based on disciplinary convergence rather than the development of new, stringently delimited disciplines"*. This should be done through the establishment of a national hub-node centre structure to create a *"vibrant, networked and transdisciplinary"* community.

Centre for Digital Life Norway

Centre for Digital Life Norway (DLN) is a national (and virtual) centre for biotechnology research and innovation that was established in 2015. DLN is a result of the Research Council of Norway's strategic priority Digital life – convergence for innovation. The Centre involves participants from across Norway under the leadership of the three universities: NTNU, University of Oslo and University of Bergen. The universities are hosting the Centre together. The Research Council has allocated 250m NOK to DLN.

The goal of DLN is to build a strong, coherent and lasting national platform for transdisciplinary biotechnology aligned with – and supporting/supported by – institutional efforts. This will be done by building a strong culture for innovative thinking and innovation; integration of society and academia and industry; training and education of a new generation of transdisciplinary life scientists in accordance with the Digital Life mission; mutual knowledge transfer supporting existing and emerging industries; and convergence across all relevant research disciplines. DLN will incorporate Responsible Research and Innovation in its activities.

The centre is managed by a networking project, consisting of five work groups which reflect the focus areas of DLN. During the first year, the work has to a large extent been focusing on the establishment of the hub-node network and the governance of DLN. Coordinators have been employed, a web page developed, and DNL has also held different conferences and seminars for the stakeholders. In autumn 2015, the first call for researcher projects connected to DLN were announced. In total six large research projects were selected from 47 applications. The projects started in 2016 and have received 20m NOK or 40m NOK each for a period of five years. In February 2017 another six research projects were granted funding with up to 20m NOK each.

Another part of the centre is the Digital Life Norway Research School (DLNRS), which is a consortium between different universities with NTNU as the hosting university. The Research School is open to any PhD students and postdocs at a Norwegian institution who feels that their project is related to digital biotechnology and life sciences.

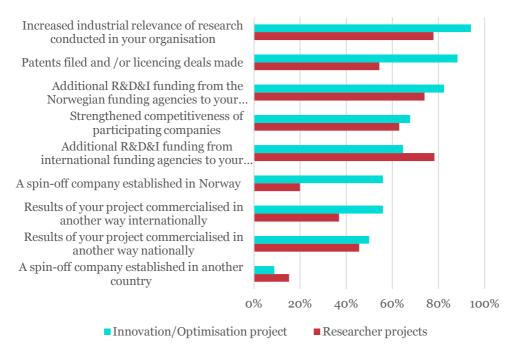
An example of one the activities that has been conducted is a recently published study that analyses the status of the digital biotechnology, focusing on opportunities for value creation, competence needs and challenges in innovation processes. Over 150 companies and R&D performers have contributed to the study, and the results show, for example, that digitalisation can reduce the time and costs for development. It also shows that digitally oriented biotechnology companies have fewer challenges in terms of innovation and commercialisation.

4.3 Programme's contribution to societal and commercial innovation and value creation

The survey supports the longer-term view of the participating organisations in seeking not only the scientific outputs from their projects but also societal and industrial relevance of their research results.

More than 90% of innovation/optimisation projects and 78% of researcher projects seek some form of industrial relevance (see Figure 11). In addition, 50% and above of respondents from the innovation/optimisation projects expect the results of their projects being commercialised in some other way internationally or nationally. Researcher projects are notably less focused on commercialisation of their project results internationally (only c.35% noted that); but they are more positive about a possibility of their results to be commercialised nationally (c.45% confirmed that). Innovation/optimisation projects by nature are more focused on delivering commercial value. Not surprising, however, that the respondents from this group of projects confirmed more (compared to the researcher projects) that they expect to establish a spin-off company in Norway coming out of the research results of their projects; or file patens and secure licencing deals.

Figure 11 Respondents' view on what industrial / innovation results they expect their projects to achieve

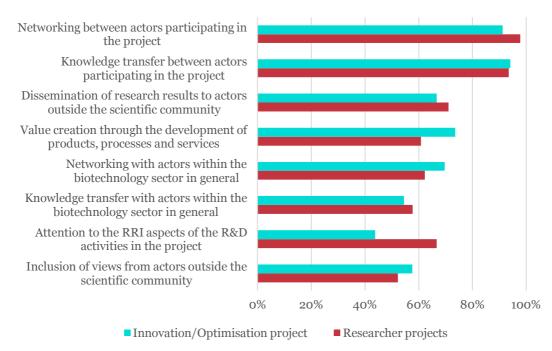


Source: Online survey. Note: Share of respondents who answered "Agree" and "Strongly agree".

In addition to the above-mentioned contribution to commercial innovation, various BIOTEK2021 participants have also mentioned that the programme and their funded projects allowed (or will allow) them to ensure knowledge transfer and networking between the actors participating in the project and within the biotechnology sector in general. These, in their turn, should also contributed to an increased potential for commercial innovation and value creation.

A potential for societal impact is also present but is somewhat different between the types of funded projects (see Figure 12). On the one hand, the respondents from researcher projects see larger increases in dissemination of results to actors outside the scientific community (71%) and attention to the RRI aspect of the R&D activities in the project (67%) than the participants of the optimisation projects. On the other hand, the optimisation projects tend to include the views from actors outside the scientific community more than the researcher projects.

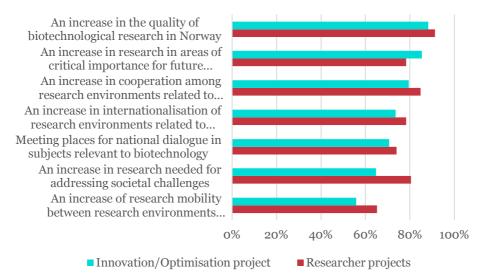
Figure 12 Respondents' view on the contribution of their project



Note: Share of respondents who answered "strongly agree" or "agree".

What the participants of all types of projects strongly agree on is that the BIOTEK2021 programme as a whole creates meeting places for national dialogues in subjects relevant to biotechnology and contributes to an increase in research needed to address societal challenges (see Figure 13).





Note: Share of respondents who answered "strongly agree" or "agree".

Innovation as indeed societal potential of their research is nicely seen in the following case study.

Two projects to support the development of tests for improved prostate cancer management

Within the remit of the BIOTEK2021 programme, RCN funded two projects to establish a urinebased molecular diagnostic test for improved prostate cancer management based on patented exosomal protein biomarkers.

Inven2, the TTO of the University of Oslo and Oslo University Hospital, has an overall ownership and responsibility of the urinary exosome test project making sure the commercial potential of the project is realised. Scientists and inventors are based at the Institute for Cancer Research, Oslo University Hospital. Aker University Hospital with its clinical staff at the Urology clinic provides clinical advice and clinical sample collection from their prostate cancer patients. Prostate cancer physicians and other key opinion leaders are consulted throughout the project. However, the science behind this project was developed during another BIOTEK2021 funded project Microvesicles as a source of prostate cancer biomarkers. It ran for three years but continuation was important to achieve more solid results and utilise generated intellectual property.

The urinary exosome test project is one of the projects funded from a joint call, funded equally by the Research Council and the Norwegian Cancer Society. The Society has been running a seed investment fund for early stage biotech research since 2013. Many companies were funded but these were too young and not pushed enough to bring commercial results. It was, therefore, important for the Cancer Society to ensure a future pipeline. One way to achieve which was by putting more funding into cancer research. A cooperation with RCN allowed this to happen. Total 56mNOK was distributed over three years with the aim to take promising and innovative research to cancer patients faster. Out of 16 submitted applications, seven projects were funded. Project ideas had to be based on previous research; had a good commercial potential; a good societal benefit and involve "users"; and a need for the development and conceptualisation of the technology to a commercial application.

A condition from the Cancer Society was for the TTOs to take the leadership of the project to ensure that these projects did not turn into the researcher-led initiatives but become companies or end up in licencing deals. For researchers, testing and validation often feels less rewarding than basic research, and patenting and work of biotech/ pharma companies is too new. The role of the TTO is, therefore, crucial in this process.

At the end of the project, apart for academic publications and patents, the team expects to have a prototype product, identified and validated the primary clinical utility for the prospective test and established a route for commercialisation of the product. When researchers are involved publishing stays an important goal. In this project case, the topic is highly hot in cancer researcher and the involved researchers want to publish. How this fits or contradicts the commercialisation goals is to be seen. Nevertheless, the results so far indicate that there will be a new spin-off project as a natural extension of the current project looking at other classes of molecules that service biomarkers.

The Expert Group notes that BIOTEK2021 has allocated almost half of its funding to researcher projects and when examining the titles of the funded researcher projects, they all do appear to have an industry oriented profile relevant to the programme. As a specific objective is to increase the collaboration between businesses and research sectors, such attempts should be applauded. At the same time, the Experts notice that although some companies are partners in large researcher projects it seems that rather few companies have received funding from the BIOTEK2021 programme, particularly when compared with the NANO2021 programme. The fact that very few IPN projects have been funded can be seen as a result from task sharing with the BIA programme, as described in section

3.1. Since the financial analysis only shows the companies that are project managers it may be that more companies participated in projects in other ways. One important thing to consider in this context is whether Norway has a business sector and a research sector which are compatible and able to work together in the ways demanded by the programme. It is critical for a successful commercialisation of novel innovation in Norway to also consider the structure of the national business sector. Without a strong and compatible business sector able to work together with the research teams in the programme there is an increased risk of commercialisation failure or that funded projects are commercialised outside the country.

However, the Experts find it disturbing that a small fraction of the participants in the researcher projects may not see their projects contributing to the value creation (see Figure 14). Around 10% of the participants do not agree with the statement that "Increase value creation through the development of products, processes and services" was a motive for participating in the project. At the same time, almost 50% of the researcher projects do not see that the programme setup allows them to get needed help (e.g. mentor, sign-posting) for the commercialisation aspects. There are many comments among the project managers that the TTOs are not supporting development efforts enough. However, there are few critical remarks about the optimisation funding and it appears to have worked well.

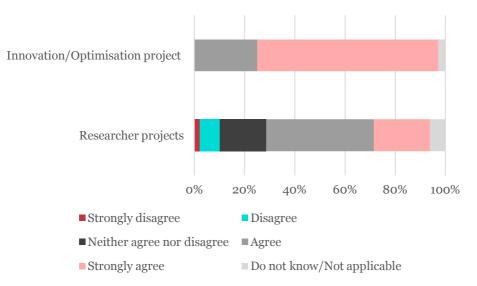


Figure 14 Participants' view on the statement "Increase value creation through the development of products, processes and services" as motive for participating in the project

Source: Online survey.

4.4 Programme's contribution to Responsible Research and Innovation

Responsible Research and Innovation (RRI) is a strategic priority under the BIOTEK2021 programme. The survey participants indicated that their participation in the programme increased spreading information about RRI with their community, changed their attention towards RRI and strengthened their awareness of RRI. Researcher projects were more positive than the innovation/optimisation projects towards the RRI topic.

However, more efforts are needed for participants to fully embrace this concept. The results of the conducted survey demonstrate a divided opinion among project applicants with regards to their attention to RRI. As illustrated in Figure 15, over 60% of the researchers projects either "Agree" or "Strongly agree" with the statement that their project has increased attention to the RRI aspects of the R&D activities. Whereas this group among the innovation/optimisation projects is just over 40%. This difference can probably be explained by the researcher projects' group 'strengthened' with a presence

of the Digital Life Network (DLN) projects, where RRI is a highly integral part. DLN plays an important part in this process and many researchers have very high expectation from DLN. In view of some of the respondents, a strong RRI focus in many DLN project should provide enhanced understanding of what RRI really is in a practical sense.

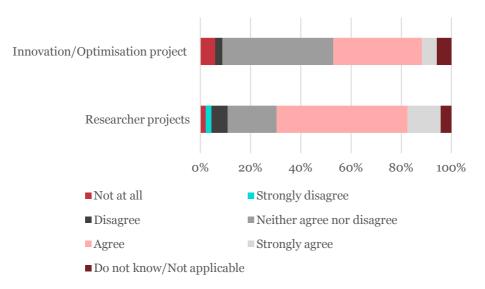


Figure 15 Participants' view on attention to the RRI aspects of the R&D activities in their project

Source: Online survey.

Many respondents confirmed that RRI as a term was not previously present among many researchers working in Norway and thus found the inclusion of the RRI into the project application and project itself extremely useful (albeit perhaps confusing at the start). It seems that the inclusion of RRI has also served to help introduce the RRI paradigm into the vocabularies of researchers who, because of the nature of the application process have even sought to gain a better understanding of RRI principles themselves.

I was little aware of the RRI concept before the proposal process that led to the funded project. The process/project and its role in the DLN has led to a better understanding of the RRI concept, including revealing its chances, but also its challenges. (Funded project applicant)

There are some success stories of researchers working on projects funded from BIOTEK2021 who have experienced a change in how they (and their colleagues) conduct research. The less vocal (though admittedly larger portion) of those who recorded their opinion through the online survey gave the impression that various events, organised during and because of BIOTEK2021 funding were contributing towards disseminating the ideals of RRI. A workshop in Lillestrøm in 2016 was mentioned as one such useful event. The main notion with these successes is that over time attitudes do change and it is important for RCN to continue to introduce RRI as a principle for other programmes to disseminate this among the scientific community.

Enzyme development for Norwegian biomass – mining Norwegian biodiversity for seizing Norwegian opportunities in the bio-based economy (NorZymeD)

In 2012, RCN allocated funding for large-scale industry relevant researcher projects with focus on biotechnology as an enabling and multidisciplinary technology. One of the five projects that received funding was project NorZymeD. The project idea was developed specifically for the call. The project started in December 2012 and is running until the end of 2018. A consortium with leading research groups in Norway was set up involving six academic partners and two industry partners. The Norwegian University of Life Sciences (NMBU) is leading the project. Over the years, small companies have also become involved in the work by separate agreements. The total budget of the project is 55m NOK, of which the Research Council's part is 40m NOK.

The main objective of the project is to develop competitive enzyme technology for processing of Norwegian biomass, to increase value creation in the Norwegian bio-based industry. The project focuses on developing enzymes and processes for biomasses and value chains where Norway has clear competitive advantage, primarily lignocellulosic biomass and marine co-products from fisheries and aquaculture. It thus involves enzymes for blue and green biotech or biomasses. Furthermore, the project focuses on building generic expertise in enzyme development and bioprocessing.

One of the secondary goals of the project is to identify and deal with ethical, social and legal issues by building ELSA capacity throughout the consortium. A dedicated work package was created for this topic. The work is led by the Centre for Philosophy of Science at the University of Bergen. The bioprospecting issues are central in the project and there are still some unresolved and significant issues in this field, related to "benefit sharing". The project has been working with activities related to ELSA and RRI in several ways, and substantial time has been devoted to these questions during project and annual meetings. One of the results from the work is a joint article on benefit sharing, with co-authors from the University of Bergen and NMBU, which was published in 2016. Another activity that has been carried out in 2015 is a so called 'walkshop' where representatives of the project, the Centre for Digital Life and the Research Council were walking for three days and discussing issues related to the future of biotechnology.

However, there is also a large group of project participants and applicants who felt that RRI received a 'tick the box' approach in the project application. Such an idea that RRI is an arbitrary inclusion led to a fair amount of criticism directed towards the application process. In particular, the most vocal criticism expressed the notion that the scientific community is well aware of the RRI principles and has already been working under this paradigm well before the BIOTEK2021 programme has started.

The external Experts note that in general, survey respondents positively view workshops and other events on RRI and perceive the evaluation of grant proposals about its RRI elements as fair. However, the RRI theme seems to have created polarisation. While many respondents are very positive, others are really very critical and see it as offensive that such an agenda suggests that scientists are not responsible by themselves. There are some descriptions in which the RRI experts and parts of the RRI is described as a clique which positions themselves to have power to decide what is "good" research and what is not.

The understanding of what RRI can contribute to projects in a positive way has not been sufficiently explained to researchers. It has been introduced as a new, compulsory aspect to be included in any project, implying that it was needed as a corrective to research that has been ongoing for a long time (suggesting that that research until that point was not or not sufficiently responsible and that researchers have not been able to conduct their research in a sufficiently responsible way). That has led to a negative connotation of RRI and scepticism among many researchers. (Funded project applicant)

This leads to discussing what seems perhaps to be the most significant barrier for RRI in Norway at this moment is a lack of communication and clear understanding of what RRI is exactly, what is set to achieve and why it is crucial to incorporate RRI. The Expert Group confirm that while this is no doubt true, it also points to a fundamental conflict about governance of science which has been particularly pronounced in the global controversies on biotechnology. The basic distinction in this conflict is whether society can and should trust science to regulate itself or whether it is necessary for society to impose regulation from the outside. The negative assessment of RRI by some of the respondents seem to be based in a fundamental value that science must be governed by scientists themselves. Such a value is not necessarily overcome by communication in the form of more information about the RRI agenda. Rather it points to a basic political discussion about whether science is and should be within democratic control. While the RCN's RRI framework is based on an integration model of the science and society relation, criticisms are based on a separation model.

4.5 Programme's alignment with national strategies and international trends

Another question for this evaluation was to look at how well the BIOTEK2021 programme has so far met research policy priorities and national needs and trends as well as how it correspondents with the international trends in the biotechnology field.

When reviewing the programme's alignment with research strategies it becomes evident that the programme should be seen in a larger context, supplementing other RCN programmes and funding instruments. BIOTEK2021 represents only 15% of the Research Council's funding for biotechnology R&D. Several other thematic programmes are instrumental in supporting this research field. FRIPRO and the Programme for User-driven Research-based Innovation (BIA) are two such programmes; Centres of Excellence (SFF) and Centres for Research-based Innovation (SFI) support several centres in the biotechnology field. Norway participates in several joint international programmes in which biotechnology constitutes an important part, such as, the Eurostars Programme. More so, funding is also allocated directly from the government (to the institutions), Innovation Norway, and from industry-specific research funds as well as trade and industry. BIOTEK2021 seems to function complementary to other thematic programmes; thus ensuring that all links in the value chain can be funded and ensure that there are no gaps in the development cycle from research to commercial products, goods and services.

The programme also seems to be positioned well internationally. Most project participants who took part in the online survey believe that BIOTEK2021 is aligned well with the current developments in the biotechnology field internationally. Out of all the respondents 86% working with researcher and 89% working with innovation/optimisation projects expressed such opinion. These results were significantly lower for the non-beneficiary category where only 61% held the same opinion.

The BIOTEK2021 programme and calls are in line with national and international needs for new knowledge and technology to help solve some of the most threatening situations to global health and needs. One example is antimicrobial resistance. (Funded project applicant)

A few respondents also commented on how the programme contributes to Norway's international visibility in the research field. A particular note was for funding of project working in the field of genetics which were commented as being in line with the trends in biotechnology research. To others the transdisciplinary nature of the programme was a good reflection of international trends in research.

However, other survey respondents were more critical over the BIOTEK2021 programme and its international dimension, arguing that the programme did not reflect the latest global developments in biotechnology research (however, concrete examples were not provided). Another criticism was around incorporating too many fields under one programme, diluting thus a focus from pure biotechnology. Some of the criticism related to this "dilution" was aimed at the perception that the programme had artificially created research fields which caused unnecessary split, questioning the potential value of these research fields. It was suggested that the programme would benefit from

greater focus on biotechnologies to strengthen the research that could be conducted under the BIOTEK2021 umbrella.

External Expert Group also commented on this issue. Differentiation can be a good strategy if the point is to make sure that a smaller country has sufficient competence within all knowledge areas to utilise and benefit from technologies and knowledge created in the entire global research system. However, a sufficient knowledge level in research areas is not necessarily the same as being an innovation leader or even being technologically competitive at a global level. Often this needs investment at a different level at the same time as it also demands an infrastructural match between business structure and research excellence in the country. Such an infrastructural match cannot simply be created over a short span of years even if the investment is massive. It is instead a long-term investment (decades) of a very large kind. Differentiation can therefore be a challenge for a small economy with limited resources, and it is a common theme among research policies to talk about prioritisation in order to strengthen areas of national or regional strength.

4.6 Programme additionality

Having discussed some of the contribution delivered by the BIOTEK2021 programme to the scientific, commercial and societal positioning of the Norwegian biotechnology research, the questions which arise are: How crucial BIOTEK2021 has really been? Did it change the behaviour of the project participants? What would the biotechnology research landscape in Norway look like if it has not been for the programme? In other words, what any evaluation of this type should look into is the additionality of the programme. It is with this in mind that a part of the online survey focused on investigating where the research ideas and applications for BIOTEK2021 came from and how much they were linked to the predecessor programme FUGE.

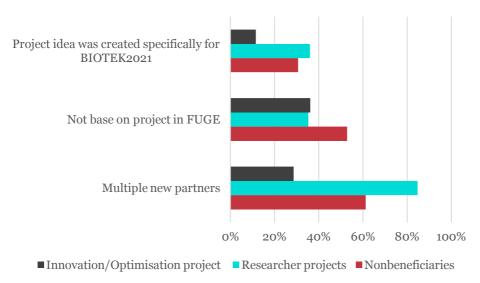
The BIOTEK2021 programme is linked to the former large programme FUGE. The evaluation of FUGE concluded that the programme has contributed to making Norwegian biotechnology research more internationally competitive in selected areas but recommended including an increased focus on internationalisation, more cooperation and communication with the business and focus on developing research excellence in selected areas – topics which are clearly visible in BIOTEK2021. Hence, when looking at BIOTEK2021 from the perspective of funding of research and innovation in biotechnology, one of the principal aspects to consider is funded projects that were made possible because of the applicants' experience from previous projects funded by FUGE.

Some other observations from the survey include:

- The majority of projects proposals were based on ideas that were in development prior to the call in BIOTEK2021
- When choosing partners for projects in BIOTEK2021 researchers are more prone to include new partners (whom they never worked with before) compared to organisations involved in innovation/optimisation projects

A large share of projects seems to be a continuation of previous work (partly funded by various programmes from RCN) and most often not created specifically for the calls for which they were submitted to and did in the majority of cases (except for researcher projects) not include several new partners. How many projects in the programme that can be considered as novel or tailored to the programme (i.e. not based on results from FUGE, created specifically for the BIOTEK2021 call and/or containing several new partners) is of course difficult to determine without going into the specifics of each funded or rejected project. However, the survey results suggest that these projects are more likely to be found among the researcher projects and rejected project applications, rather than among the innovation/optimisation projects, see Figure 16.

Figure 16 Share of projects designed specifically for the BIOTEK2021 call, not based on results from FUGE and/or containing multiple new partners



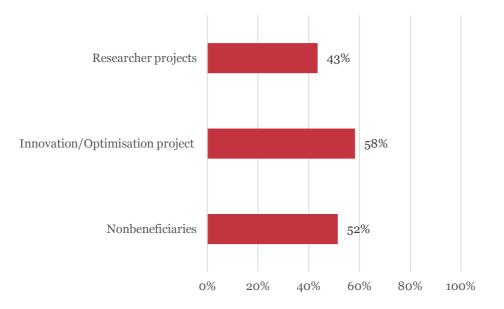
Source: Online survey.

The survey results show a clear difference between funded and non-funded projects. Whereas the activities of the majority of funded projects (c.60%) are based upon the knowledge developed under FUGE; it is the opposite in case of the non-funded projects. A link to the FUGE programme or at least some of its activities also partially explains that most of the project ideas were in development prior to the BIOTEK2021 call. In case of innovation/optimisation projects which took part in the survey more or less all the ideas were in development prior to the call. This is probably linked to the fact that before focusing on taking a project idea closer to the market or commercialisation, substantial research efforts had to be put in place meaning that the project idea was under development months if not years before the call. Whereas in case of the researcher projects, nearly 40% of the projects had ideas which were created specifically for the call. This is again not surprising given that BIOTEK2021 is set to support new research ideas as well as the further development of already existing research. The purpose with this question was not to find out the exact moment when an idea for a project was conceived; but rather to establish a link and some sort of continuation between FUGE and BIOTEK2021. In other words, if BIOTEK2021 was not introduced, some of the research idea which have reached certain level of development under FUGE might have struggled for funding.

There is no doubt that the BIOTEK2021 funding was important for the majority of the applicants. More than half of the participants in the researcher projects (who responded to the survey) stated that their project would not have happened if it had not been for the RCN funding. The majority of the innovation/optimisation projects felt that they would have had to reduce either the scope, the duration or the composition of their project consortium if they had not received the RCN funding.

It is interesting to compare the hypothetical responses from the funded projects with the answers from the project applicants who were in fact not successful. As shown in Figure 17, twenty funded researcher projects (43% of those which took part in the survey) and 23 innovation/optimisation projects (more than 58%) would have taken place even without the BIOTEK2021 funding (although in a somewhat reduced form). That is in line with what has actually happened to the rejected projects, where 17 projects (or 52% of those which participated in the survey) stated that their project indeed was conducted or is ongoing (in a reduced form) subsequent of the unsuccessful application to BIOTEK2021. With that in mind, the assessments made by the funded project leaders seem quite accurate.

Figure 17 Share of project leaders who assess that their project would have been conducted even without funding from BIOTEK2021, though with either with a different scope, fewer partners or during a longer time span



Source: Online survey. Note: For the non-beneficiaries the responses reveal what actually happened. The non-beneficiaries consist of both researcher and innovation/optimisation projects.

It is not known for sure what type of funding the rejected projects eventually got, but the ones who answered that question in the survey mentioned other RCN programmes, other public funding means or private sources. More than 80% of funded projects were put forward for alternative funding sources when preparing the application to BIOTEK2021. Judging by the comments, the principal choice of funding was the EU Horizon 2020 programme, ERA-NETs, and various national sources from RCN and other organisations, e.g. HAVBRUK, FRIPRO, NANO2021, Helse Sør Øst Innovation, MABIT, Novo Preseed, the Cancer Society funds, ELSA call, FORNY and FRIBIOMED.

The majority of organisations involved in innovation/optimisation projects state that the programme to a large extent coincided with what they wanted to achieve with their projects when preparing their applications in response to the calls. The majority of the participants in the researcher projects felt that the programmes coincided to some extent; whereas not-funded project applicants felt just a small alignment between the programme and their own expectations. Without going into the details of individual projects it is difficult, however, to explain the reasons between these changes.

Although access to funding was an important reason for applying to the BIOTEK2021 programme, it was not named as the key reason. Representatives of the researcher projects indicated an opportunity to establish or strengthen cooperation with a research institution as their prime motivation for funding application. After access to funding (which was on the 2nd place) came such reasons as contribution to tacking societal changes and an opportunity to access networks with other R&D providers. Representatives of the innovation/optimisation projects marked an opportunity to increase value creation through the development of products, processes and services. Access to funding was ranked 2nd too and preceded an opportunity to establish or strengthen cooperation with companies.

The difference between the two groups is not that surprising. Apart from funding (which is a reasonable and understandable goal for the novelty driven projects) and tacking of societal challenges (which all research groups irrespective of the key goals of their projects try to keep in mind), the other reasons show a natural difference between the two groups. The researcher projects are focused on R&D cooperation, access to R&D networks, and recruitment of researchers and PhD candidates. The

innovation/optimisation projects are aiming to develop a product, process or services, establish links to companies but do realise that this needs certain cooperation with research institutions.

4.7 Administration of the programme

Finally, this evaluation was set to look into programme administration. The assessment of this question is based on the feedback received from funded and rejected projects.

Beneficiaries demonstrate a general high level of satisfaction with the RCN's administration of the programme and comment highly on the support received from RCN during the project implementation, clarity of the call and requirements for project reporting.

Nearly 80% of funded innovation/optimisation projects believe that the programme provides them with the necessary support to produce results that could be commercialised. There is always a room for certain improvements, e.g. one funded applicant states that "additional funding could be made available to stimulate commercialisation of the results after the completion of the project." In case of the researcher projects only half of the survey respondents share that opinion. This is, however, understandable given that the key goal of these project is to focus on research rather than potential commercialisation and as put by one of the respondents: "The focus should be on science and not on everything else."

However, stringiness of the assessment as compared to other programmes is questioned by some of the survey respondents. No big difference is observed between the researcher and innovation/optimisation type projects. However, the leaders of the rejected projects are of different opinion. Although their larger proportion (compared to the funded projects) found the calls for proposals clear; more than half of them doubted the transparency of the proposals' assessment and selection of projects and were not convinced that relevant expertise was involved in the assessment. Insufficient information about reasons for application rejections and communication of such information are mentioned as weak points. The rejected applicants seem to find out about their unsuccessful application days or even weeks after the successful projects were announced in the public domain. The rejected group would have preferred to be informed earlier. Unclear communication of reasons for rejection was also strongly noted. According to some of the rejected applicants they were referred to read the guidelines for the applications better in order to understand why their project was not selected. Many applicants think that the feedback RCN provides is rather cursory and the Council rarely advises on how an application can be improved.

Most project leaders state that active projects are progressing as planned. Of course certain changes and obstacles occur in some of the projects (which is a normal 'way of life' for various projects) but that should not result in major problems. Among the reasons behind some of the delays the following were mentioned: the granted budget was lower compared to the one the projects applied for; delays in accessing the university infrastructure; the nature of project itself; problems in recruitment. Generally, beneficiaries appreciate RCN for their general tolerance with arising changes during project implementation and for the support provided:

I am extremely pleased with the extra effort RCN puts into the administration of the BIOTEK2021 programme, including the close follow up on progress beyond the mere reports that are filed, and the offering of courses to the Project leaders of Projects in the programme. (Funded project applicant)

5 Conclusions and recommendations

5.1 Concluding remarks

At the start of this last section it is useful to remind the reader about the purpose of this evaluation:

To assess how BIOTEK2021 through its choice of priorities and instruments has worked so far in achieving its set objectives and if priorities between different instruments of the programme given a project portfolio that contributes to the achievement of the programme's objectives.

In short: Is the programme on the right track? The evaluation team together with the external Expert Group believe that the programme has worked well so far in following the set goal and objectives in a continuous manner. The administration of the programme listened to its users, had an active internal evaluation process, showed flexibility and introduced novel funding opportunities during the period to further improve the chances of a successful programme.

The programme has supported different types of projects in an active and flexible way targeting the achievement of the set objectives. Almost half the funding has been allocated to researcher projects which are R&D projects designed to promote scientific renewal and development of disciplines and/or to generate new knowledge about issues relevant to society. The major part of the researcher projects is five large-scale, industry relevant researcher projects which focus on biotechnology as an enabling and multidisciplinary technology while only very few are traditional researcher projects. BIOTEK2021 also funds optimisation projects to support research and development of biotechnology products, processes and services that have commercial potential, and where there is a need to develop and conceptualise the technology to adapt it to commercial use. The programme has funded initiatives, like Idea Labs to bring forward new and innovative ideas in the interfaces between different disciplines and strategic initiatives as the Centre for Digital Life Norway. The programme also supports European joint calls and to a lesser extent events.

As an integral part in the development of the National Strategy for Biotechnology, BIOTEK2021 focuses on delivering innovation in four thematic sectors: 1) marine biotechnology; 2) biotechnology in agriculture; 3) medical biotechnology and 4) industrial biotechnology. Basic research is not supported by the programme. The primary objective for BIOTEK2021 is to generate biotechnology that contributes to value creation and innovation to solve societal challenges in a responsible manner. To achieve this objective a set of secondary objectives has been defined, which enable to better measure how the primary objective has been met. The six objectives capture the key elements essential for any type of a programme supporting science-driven research but also aiming to generate commercial and societal benefits. These key elements are Scientific Excellence, Differentiation, Innovation, Societal Challenges, Collaboration and Responsible Research and Innovation.

The evaluation team supports the external Expert Group in their assessment of the programme in relation to these set objectives.²⁸

5.1.1 Scientific excellence

Both the evaluation team and the Expert Group concur that it is still too early to evaluate such deliverables as publications, citations, patents, licensing agreements and established SMEs. The projects in the programme need more time to generate measurable results and impacts. As such these were not considered in this evaluation. There is a list of already achieved publication outputs, which is bound to increase even further and lead to the improvement of scientific excellence (as has also been confirmed by the participants of the projects, who took part in the online survey). A strong competition exists for the available funding – a competition, which is based among other on excellence and as such should also lead to scientific excellence.

²⁸ A full Expert Report can be found in Appendix A.

Both teams believe that in addition to the traditional bibliometric outputs, a strong presence of the Norwegian research teams in various European networks can also be treated as a contribution to the increasing scientific excellence in Norway. This seems to be working well, particularly due to the specific funding in BIOTEK2021 linked to the ERA-nets. More so, in the explicit goal to foster excellence and innovation, the decision was made to setup the Centre for Digital Life Norway (DLN) and to allocate a third of the funding for this initiative. This is discussed further in the section.

5.1.2 Differentiation

It is an explicit objective of the programme that each sector's special needs should be met and be allocated at least 10% of the programme's portfolio. In general, this is a very positive response from the project participants further pointing to the programme's fit with the demand for R&D in the national biotechnology field. As commented by one participant:

Subjects cover both the grand global challenges addressable by biotechnology and national strengths and capacities. Project calls take into consideration the recognised possibilities within transdisciplinary research. (Funded project participant)

Some topics were especially mentioned, e.g. reverse genetics in solving problems in biological production, new knowledge and technology to help solve some of the most threatening situations to global health and needs (e.g. antimicrobial resistance), interaction with IT and the interface with other key enabling technologies.

Marine biotechnology is given a special place and should be awarded at least 25% of the portfolio. With regard to the marine sector the goal is reached, but other sectors are quite different from each other in terms of size in the programme portfolio. For example, the agricultural biotech so far has been awarded only 7% of the funding. The Expert Group states that this, however, is not necessarily a problem as the allocation of funds is based on criteria of excellence and relevance. It is thus assumed that green biotechnology has been awarded funds according to the quality of the applications in this area. The Experts encourage to consider whether the programme's objectives should keep the ambition of spreading the available resources over all sectors and give an example of the medical sector.

The medical sector is a sector with high priority in most countries and is internationally highly competitive. So far, this sector has received most support from BIOTEK2021 (41%). Considering the lack of a strong and established business structure in Norway for the medical sector as well as the fact that a major part of the innovative concepts and SMEs have not generated lasting economic return it can be discussed if the funding could better be used in other sectors where Norway is more competitive and has a more established business structure.

5.1.3 Innovation

As a programme with clear industry-oriented profile, a focus on or at least a potential for innovation can be seen in all the activities of BIOTEK2021. As nicely summarised by one of the participants:

BIOTEK2021 provides a unique possibility to bridge the gap between basic research and industry involved development of new discoveries, aiding translation of research to a commercial product.

However, a worrying signal is an observed somewhat missed perspective on innovation among some of the researcher projects, whose representatives in their survey responses indicated that they did not see value creation through the development of products, processes and services as a motive for participating in the projects. As such, perhaps this is not surprising as one would expect researchers to think more about scientific rather than commercial application about their research. However, since the BIOTEK2021 programme is supposed to have a distinctly industry-oriented profile, one would perhaps expect higher appreciation of the potential to commercialise results of the research – even when it comes from the researcher projects.

5.1.4 Collaboration

It is a specific objective of the programme to increase the collaboration between businesses and research sectors. This is an obvious goal and should be applauded. Collaboration has been noted in many projects funded by BIOTEK2021: between researchers of different institutions; between commercial structures of research institutions (e.g. Technology Transfer Officers) and researchers; between researchers and industry; between researchers and other stakeholder groups.

The external Experts note that collaboration is in general a "good thing" that can aid the generation of novel knowledge and ideas. Collaboration can also make the collaborating team a stronger entity that can reach goals that would otherwise have been impossible or at least very difficult to reach. At the same time as the benefits of collaboration is clear it may not always be a benefit when the collaboration is a key factor for funding and is in a way forced to the applicants. To some observers, the collaboration demands of the DLN funding has indeed seemed very bureaucratic and might have hindered other forms of collaboration that did not fit into the stipulated scheme. Compared to similar efforts internationally, DLN is more ambitious in its comprehensive approach to transdisciplinarity. The strategy has been discussed with a large group of stakeholders, so it should be safe to assume that there is an overall buy-in to this ambitious strategic goal. At the same time, however, the Experts find it interesting to consider the implications of using a funding body, such as RCN, as the key driver for a change of the fundamental collaborative processes and cultures of science. Within organisational studies it is a standing discussion whether a strategic actor deliberately can change a culture or whether culture is more fundamental and hence beyond the reach of strategic actions.

Similarly – as noted by the Experts – the DLN strategy puts more emphasis on law, social sciences and humanities as integrated in the network than what is usually seen in an international context. However, such an approach also demands a whole new role of social scientists and scholars in arts and humanities. Traditionally, such researchers have primarily been adopting a role of observers; but in the ambitious DLN strategy they need to become active partners and co-creators. It is not entirely clear how well-equipped they are to take on this new role.

5.1.5 Societal challenges and RRI

There is no doubt that all researchers and businesses should address societal challenges in a responsible way. Together with the NANO2021 programme a framework for RRI has been created and it seems that particularly the researcher projects have all demanded an RRI component, putting – in the opinion of the Expert Group – RCN, BIOTEK2021 as well as NANO2021 in the forefront internationally when it comes to the implementation of an RRI-perspective. Together with other programmes a specialised call within ELSA and RRI was announced in 2014 and RRI is a central and integrated component of the Centre for Digital Life Norway initiative. However, the Experts stress that very often RRI is seen to be a loosely connected add-on to research programmes which lead to a "box-ticking" behaviour by applicants and hence has very little impact on actual research projects. The RRI-framework developed by RCN and particularly the DLN initiative is an inspiration for other funding bodies across the world.

The external Experts also note that the RRI theme seems to have created polarisation, requiring further efforts in this area. While the RCN's RRI framework is based on an integration model of the science and society relation, criticisms are based on a separation model. Subscribing to either one of these models is ultimately a political question. One way of dealing with such a conflict is to demonstrate how the RRI agenda can be useful to science. Another is to find ways of demonstrating that the RRI agenda is not something new, but is built on the responsibilities already exercised by scientists and takes its point of departure in what scientists already do. Such an approach might seem more respectful to scientists, but on the other hand it does make it more difficult to brand the DLN and similar initiatives as internationally leading and "new".

5.2 Recommendations

Based on the conducted background analysis, empirical evidence from funded and rejected projects, in-depth telephone conversations with selected funded projects and wider stakeholders, together with

the experience of the External Expert Group generated over time and considering the international trends in the biotechnology sector, the evaluation team and the Expert Group compiled a set of recommendations.

These recommendations could help revising the programme plans for 2017 and beyond ensuring further smooth development of the BIOTEK2021 programme in line with national and international trends and expectations. These should also be useful as an input to programme management and potentially to the ministries' preparation of revised long-term research plan and the annual research budgets. Research institutions should also be able to use the results of the evaluation in assessing their own priorities and performance.

For easier use, the recommendations are presented in three groups: on project level, on programme level and on the level of programme administration. A note is also made if a recommendation came from the Expert Group, the evaluation team or if both teams share the opinion about a given recommendation.

5.2.1 On project level

- Industrial focus of the programme is very clear; yet some projects have less emphasis on commercialisation. The Expert Group concludes that some of the researcher projects appear to have a somewhat reduced attention to the commercialisation aspect but the answers in the survey also indicate that this can improve if some of the funding is allocated to include some tools (e.g. mentors, sign-posting) intended for this purpose. The Expert Group agrees that RCN should **consider including such tools** to raise the focus on this aspect. The evaluation team adds that even an **increase in support already provided** can be helpful here.
- The Expert Group concludes that Digital Life Norway (DLN) is a large commitment made by RCN and BIOTEK2021 where about a third of the funding is invested. The question the external Experts have is to whether all the innovative and specialised goals in DLN are an enabler or a constrictor of excellence. In their opinion, internationally similar initiatives have not always been a success. Therefore, the Expert Group believes that it is important to determine **if the funding on DLN is well spent or if the investment could better be used on other activities to reach the objectives of the programme**. Perhaps a reduced funding could achieve the same commitment to the collaboration effort. To get a solid justification for the re-shaping of this initiative, the Experts recommend to analyse similar national initiatives elsewhere, especially with regard to impact on research and the development of new concepts as compared to more distributed funding schemes, and to evaluated the DLN initiative. The evaluation team recommends such an evaluation to take after 1-2 years in order to allow the DLN projects to get some momentum and some results.
- Before making any drastic decision in relation to DLN, more **efforts need to be spent on information and communication activities as a way to increase the awareness about DLN and its role**. An added value of the initiative is that the experiences from DLN are spread internationally through the experts of the Centre's Scientific Advisory Board. There has also been an interest from other scientific areas in Norway for the concept that is being tested through DLN.
- Another way to make the activities and purpose of DLN known and accepted in a wider community, the evaluation team believes that RCN should **consider mobility of scientists** within Norway in general and within a particular set-up such as the Centre for Digital Life.
- A substantial effort has been put through BIOTEK2021 into linking Norwegian research groups internationally via its commitment to the ERA-NETs. It was not clear to the external Expert Group and indeed the evaluation team whether research teams funded through the ERA-NETs as a continuation of their projects also received some EU funding. It would be useful to **assess further development of the BIOTEK2021 funded projects and/or involved teams in securing EU funding**, e.g. Horizon 2020, as a way to assess longer-term impact of the national funding in strengthening the capacity of the Norwegian research and industrial teams.

5.2.2 On programme level

- The external Expert Group concludes that the optimisation projects are R&D projects that have a clear industry-oriented profile fully in line with the objectives of the programme and is perhaps the project type that have received fewest critical remarks. The chances of having some of these projects to develop into something with a commercial value and meeting the many challenges in the society should be good. As such the Group and the wider evaluation team highly recommend to **continue the support of the optimisation projects**.
- Another group of projects which seems to be working well are ERA-NETs. The evaluation team particularly welcomes that given the fact that it is impossible to fund international partners in a nationally funded project. Exposing a Norwegian research group on the ERA-NETs arena strengthens the visibility of Norwegian research internationally and allows building strong international networks. Having said that, the ERA-NETs funding is usually rather scarce (e.g. it allows to fund approximately one post-doc). By combining activities which are, for example, funded by other projects can potentially increase the critical mass. A possibility needs to be investigated to further **support ERA-NETs theme (where Norwegian researchers are participating) with some additional national thematic call to link several calls and researcher groups together and thus increase the amount of funding going to linked activities. In the NANO2021 programme NorNanoReg is one similar example "expanding" FP7 participation.**
- On another note, the Expert Group acknowledges the commitment of the national research institutions in being part of the transfer of innovative technologies for the benefit of society, and welcomes their involvement in projects may be necessary to further increase focus on the commercialisation aspects of the programme. The Experts recommend **evaluating the compatibility of different tools (***"virkemiddelapparatet"***) to ensure that the new innovation can reach their commercial potential**.
- The Experts also remind that internationally biotechnology is used for commercialisation purposes in many different areas. It can contribute to value creation from many areas of research and from many industrial areas including medicine, agriculture/forestry, veterinary science, marine resources, waste management, and many industrial processes. However, Norway has limited resources and it will be challenging to be scientific excellent in all areas of research and be successful in value creation from all areas of science. RCN has to some extent recognised this through allocating the most of the BIOTEK2021 funding to medical and marine biotechnology and less to agriculture/forestry and industrial biotechnology. Since Norway is a small country with scarce resources, the Expert Group states that it is **very important for policymakers together with the R&D institutions to look carefully at potential niches the biotechnology sector should seek to fill when making future programmes or developing products with commercial potential.**
- The opinion of the evaluation team is that one way to gradually address this question of prioritisation is to have specialised thematic calls. Such specialised thematic calls in partnership with other funding organisations will bring even more benefit. For example, in case of a joint call with the Norwegian Cancer Society, it allowed the research teams to develop and try to get the idea closer to the clinic and patients. This is of high importance especially when other type of funding cannot be used to do this type of research. Having specialised calls allow more people to get funding; but this needs to be balanced out and perhaps run in parallel with general calls. In case when parallel calls are not possible, it is crucial to advertise specific specialised calls a lot in advance. This way, research groups which are not involved in the field relevant to the call could start thinking about other funding opportunities.
- The external Experts strongly believe that considering Norwegian business structure is crucial in delivering the BIOTEK2021's ambition to develop biotechnological innovation. The national resources including competent capital should be sufficiently large to generate a critical mass necessary to create products and services with market potential. From an international point of view Norway does not have a very strong business structure in the biotechnology area (especially

medical biotechnology). The Expert Group recommends to **consider focusing on the areas where Norway has a special advantage and strength and preferably a national business structure** to better absorb the commercial potential of the programme.

- Although industry representatives are involved as partners in the researcher projects, the external Experts feel the extent of industrial participation as project managers is still limited. It is not entirely clear if the industrial participation in the BIOTEK2021 projects in other positions changes the impression of their restricted involvement. It may be that many of the companies are putting more effort on more applied (more D than R&D) projects that in part may be funded by the BIA programme. Or the time scale of projects funded through BIOTEK2021 (as indeed other publicly-funded programme) does not match those of industrial projects. However, in order to answer these questions, the whole portfolio of biotech-funded projects at RCN has to be analysed together looking in particular into the rationale and motivation of industrial partners. The evaluation team thinks that an ongoing panel evaluation of the BIA programme might have already shed some light on this topic.
- The Expert Groups further ascertains that what often happens in the biotechnology field is that a research idea with commercial potential gets abandoned because no sufficient funding is available to take it further from the early stage. One way to address this potential funding gap is to have a strong early-stage funding community in Norway which is ready to commit for long-term (and often) risky biotechnology development. The Expert Group suggests to RCN to **evaluate ways** (e.g. seminars) to help potential investors better understand the biotechnology field with its many interesting opportunities, its limitations and the risks associated with investing in projects in this field. The evaluation team supports this idea and suggest addressing this in partnership with innovation supporting actors in Norway (e.g. Innovation Norway).
- A way to link with the innovation supporting actors more can also be addressed through the **involvement of Technology Transfer Offices (TTOs) in running projects**. This is already done in case of the optimisation projects and is **recommended to be continued**. Involving TTOs as applicants and project owners should increase the chances of project ideas getting readier for commercialisation. However, what was not looked at in this evaluation are the internal regulations and procedures around commercialisation in different research organisations and how these stimulate or hinder the process. Protection and ownerships of IP, distribution of royalties in case of successful commercialisation between the owner of the idea, TTO and the host research institutions are just some of these internal regulations and procedures that need to be taken into account.
- The innovation aspects of the BIOTEK2021 programme are very clear and the programme is regarded to be future oriented, especially when it comes to RRI which is a topic that has become increasingly important over time. Regarding the calls for researcher projects connected to DLN, so far quite few and very large projects have been funded. More so, funding allocation via a large-scale programme has brought much tougher competition into the research community because it has essentially reduced the amount of available funding. This means that fewer projects and thus fewer research groups are funded. On the one hand, it supports the competitive approach which should theoretically bring higher quality. On the other hand, it allows for more experience and visible groups to win more and more; putting smaller teams behind. It could also help diversify the risks and increase the chances for innovation to occur. One way to address this challenge is to **alternate the level of funding allocated during the calls, e.g. to focus the next call on slightly smaller projects**.

5.2.3 On administration level

Several recommendations are linked to the <u>application phase</u> for the projects:

• A two-stage application process can be applied for some types of projects. This has already been tested during BIOTEK2021. During the first stage the reviewers look at the administrative side of an application before inviting the applicants to the second stage, i.e. present

the project. Such approach usually leads to a better quality of applications as if there is a lack of clarity in the application, the applicant has an opportunity to clarify things at a later stage.

- The external Experts noticed some indications that the **DLN application process may appear** rather complicated and asks for a procedure for including new partners and projects to be simplified. This should make the application for the DLN project more appealing for potential applicants.
- The Expert Group also notes that the recommendations for the hub-node structure and the way it is implemented in the calls for DLN applications seems rather complicated. It is asking applicants to align a lot of different aspects and such demands can easily be seen as overly bureaucratic to applicants. A quick review with an idea of possible simplification of the DLN application procedure could be useful.

Several recommendations are linked to the assessment of the applications phase:

- The competition for funding is tough and applicants often feel that it is a real battle to get it but the feedback they receive is not sufficient enough to understand how to improve their application in the future funding round. It would be beneficial to **review the feedback process and consider a more ambitious feedback routine**. This should help achieve higher quality and more applications thus in a longer-term contributing more to scientific, innovation and societal impact.
- **Involvement of international evaluation committees in assessing some of the applications should continue**, especially where the areas or topics require quite specialised expertise that Norway does not always have. This is already done in case of optimisation and other projects and through the involvement of international expertise within the Centre for Digital Life.

Several recommendations are linked to the projects' implementation phase:

- In view of funded projects, the BIOTEK2021 programme seems to be running smoothly with RCN having a very dedicated programme team and regularly following up on the project. To ensure that the projects achieve their set results and especially deliver them to high scientific excellence **a** half-way evaluation of each project can be helpful. This can be done by an internal RCN team when needed including some external experts to cross-check the scientific, commercial and societal progress of the project.
- When joining forces with other funding organisations, administration of the calls, evaluation and then implementation is more efficient when done from within one organisation. It can be RCN; it can be another benefactor. In case of a joint call with the Cancer Society, RCN took care of the administrative side of running the call and distributing the funding. This allowed the Society as an NGO not to spend any resources on administration showing a responsible way of using money raised from the public. For the Research Council, this cooperation increased the available funding.

Appendix A Expert Report BIOTEK 202129

A.1 Introduction

This brief report consists of three sections: A.2 Summary of international trends in biotechnology and RRI; A.3 Analysis of the objectives of BIOTEK2021 and their relation to international trends; A.4 Conclusions and recommendations from the expert group. The expert group emphasises that this evaluation is based mainly on qualitative comparisons of the project portfolio with programme objectives and international trends, survey responses from funded and non-funded applicants. Some quantitative data on programme impact have been available but since commercialisation of potential products often require more time to be realized our evaluation of these data are limited.

A.2 International trends

A.2.1 Trends in biotechnology

Within the OECD biotechnology is defined as the *application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.* Biotechnology has for centuries been a cornerstone in the development of the modern society and it will most certainly continue to have a dominant influence on our society within the healthcare sector, in agriculture, forestry, aquaculture as well as in the marine sector and also for the development of new industrial processes and products from sustainable resources.

Human health

In most if not all high-income countries improving human health is a top priority. Not surprising that a significant amount of available resources is being dedicated to this area of biotechnology. This makes the field highly competitive and challenging. In the health care sector, biotechnology tools are and will be further applied in human genome research, development of new vaccines, understanding the biology and improving diagnosis and treatment of cancers, genetics, infectious and chronic diseases and malignancies. Biotechnology will also be central in developing and applying stem cell biology as well as regenerative medicine for clinical use and in developing bioengineering further with a focus on implants and devices.

Biotechnology can help improve human health in many ways. Human genome studies can be exploited to diagnose, prevent and cure disease, to better target treatments and avoid side-effects, and to identify novel biomarkers and therapeutic targets. Biotechnology approaches can also be used in the fight against antimicrobial resistance with studies of new antimicrobial treatments, vaccines and diagnostic tools. Multidisciplinary bio-design studies (e.g. bio instruments, devices, implants, bio-imaging, and sensors) that address key biomedical challenges as well as the application of metagenomics to human nutrition and disease/obesity are further important examples of biotechnological approaches to human health.

A trend in diagnosis is the development of Point of Care (POC) tests that enable a quick but still accurate enough answer at the patient's bedside, in the operating theatre or by the patient at his/her home. POC tests facilitate and improve an accurate diagnosis when a central clinical lab facility is not available.

Sustainable agriculture and forestry

The areas of breeding, reproduction technologies, nutrition and health care are important to enhance animal health and productivity.

²⁹ The authors of this expert report are Anders Lönneborg, Päivi Teivainen-Lædre, Stefan Hohmann and Maja Horst. Together they constitute the external Expert Group assigned by RCN specifically for this evaluation. Please see Section 1. Introduction of the main report for more details.

The widespread worldwide use of antibiotics in livestock and poultry production has a serious effect on antimicrobial resistance and affects health not only of the animals but also of the people consuming animal products. Other examples where biotechnology will be useful concern breeding, animal food safety, metagenomics of the bacterial flora in the gastrointestinal track in livestock and poultry, nutrigenomics for optimisation of feed formulation, breeding for optimisation of feed utilisation, and utilisation of waste streams to create high-value proteins and fats.

Improved nutritional quality, and resistance against pests and diseases are central for the development of crops higher productivity. Breeding of crops which cope with the changing climate and the abiotic and biotic stress associated with it and the use of novel methods for breeding (i.e. genome editing) are other examples that require further attention. Developing crops to produce compounds for industrial purpose (i.e. modified starch, modified fatty acid composition, pharmaceutical compounds) should also be mentioned. Soil biology is an often-neglected field where biotechnology is likely to become even more important in the future. There are clear signs in modern industrial farming that normal biodiversity is reduced and many important organisms disappear from the soil. Metagenomics is an important tool to measure the diversity of organisms in the soil and will become a central tool in efforts to solve the challenging dilemma between maintaining a highly productive farming and at the same time maintaining a sustainable soil.

Forestry is an important source of raw material for different applications. There are features unique to forest trees that may be utilised for commercial purposes. Raw material from trees is already today used for new biomaterial and biofuel and will for sure be developed even further in the future. Cellulose, lignin, terpenes and other secondary compounds very difficult to synthesize from scratch are especially present in forest trees. Some of the special chemical compounds in forest trees are already purified and commercialised by Norwegian industry but the potential of forestry raw materials is presently not fully exploited. It is well known that cyclosporine was first obtained from a soil fungus found in Norway and there are likely also other useful compounds present in fungi, mosses, lichens and other organisms widespread in the Norwegian forests that are yet to be detected and utilised.

Sustainable aquaculture

Aquaculture is a large and growing business worldwide. This growth also means that the environmental impact of this business areas is also becoming more and more significant. In this perspective there should be an increased support to sustainable aquaculture biotechnology that can address the environmental concerns related to aquaculture and that at the same time can help enhance aquaculture productivity and contribute to food security not only in Norway but also internationally. Focus should be on research that supports improving feed and nutrition, aquatic health and breeding techniques.

Examples of project areas of interest include health of the aquaculture environment, prevention and cure of diseases, rapid diagnostic tools, breeding and genetics, antimicrobial resistance (new antimicrobial medicines, vaccines), mucosal immunity, studies on genome edited salmon (e.g. health issues, environmental questions and considerations about the consequences of accidental release of genetically modified fish into the ocean), technology and innovation facilitating increased production within biological and environmental constraints.

Bioprospecting marine resources

Large sectors of the marine ecosystems remain unexplored with respect to novel compounds and raw materials. Many countries have realised this and are devoting significant resources to explore the potential value these ecosystems may hold. Norway has access to many unique marine ecosystems and could utilise this great advantage to the best for the society. Examples include marine algae as a source for biofuels, different features of phytoplankton and extremophiles, discovery of novel microbial enzymes and biomaterials with special features. Value creation based on by-products, waste streams and effluents from fisheries and farming industry should also be explored in Norway as it is done in other countries with a significant marine business sector. The application of metagenomics of bioactive molecules and whole genome sequencing of native commercially important aquaculture species to

generate novel and applicable knowledge is also an international trend to increase value of the products. Much remains to be discovered on the many unique features of the marine ecosystem and its diversity of life forms.

Nanobiotechnology

The combination of life science, engineering, and technology conducted at the nanoscale is gaining rapid attention and these multidisciplinary approaches for engaging in knowledge exchange towards targeted innovation is an international trend that Norway should follow closely. Nanotechnology is funded by the Research Council through a dedicated programme; however, when nanotechnology is now being applied in living organisms it is becoming more integrated with biotechnology. Nanotechnology is to be applied to new therapeutics and targeted drug delivery vehicles, when developing novel formulations to enhance the efficacy of existing drugs and to expand their therapeutic spectrum, for novel diagnostics and imaging tools aiding an early disease detection, for sensors to detect chemicals, toxins and pathogens. Nanotechnology could potentially also be used to assess and evaluate impact of bio-plastics and for bio-based plastic production. There will also be a need to develop technologies to detect micro- and nanoparticles.

Industrial processes

Biotechnology has many applications to help improve different processes in the industry. It can greatly influence the development of more sustainable products and materials. Increased use of life-cycle analysis of products with a view on sustainable production is gaining increased attention worldwide and should also be stimulated in Norway. Biotechnology can further be applied to exploit the biosynthetic and bio catalytic capacities of the microbial communities to improve waste management, pollution mitigation, and for bioprocessing of indigestible biomass and production of biofuel from renewable resources. Metagenomics can help maintaining the fresh water and marine environments as a basis for a sustainable production and at the same time create an added value in the production.

A.2.2 ELSA and trends in RRI

Biotechnology has been the focus of public controversies for decades. This was the driver for a decision to include research on the Ethical, Legal and Social Aspects (ELSA) in the original Human Genome Project. Currently, these controversies seem to have somewhat "cooled off" compared to the heated global controversies seen around the birth of Dolly and the export of GMO to Europe in the 1990s. However, such controversies should not be viewed as a phenomenon that follow a linear development. Rather, they must be understood as the expression of deeply seated value-based political disagreements over the role of science in society. They are not simply disputes over the technology, but stem from the fact that while most people in western society perceives science to be a solution to societal problems, others see it as the cause of more problems than solutions.

Controversies about biotechnology has been one of the driving forces for the development of an agenda of research and political action on the improvement of the relationship between science and society which is now covering all scientific research. This agenda has been particularly strong in the EU. In the UK three cross-institutional centres for ELSA research in biotechnology were funded in the 1990's with a very large investment from the British research councils. Since then the UK has played a leading role in such research and in the development of the ELSA-programme into a multitude of research agendas in law, economics, social sciences and humanities.

In the EU during the last decade a focus of science in society has been developed into the "responsible research and innovation" (RRI) framework. While this term has achieved a certain stable usage, it covers a loosely defined set of phenomena, and is being developed and implemented differently in different contexts. Generally, its most stable and entrenched usage can be found in policy circles within the EU while the concept has a more precarious life in other national contexts.

The concept of RRI has been particularly important in the Horizon2020 framework, where it has been the focus of specific actions as well as a cross-cutting issue to be addressed and promoted in many other framework objectives. What the experience from Horizon2020 demonstrates is that the

interpretation of the idea of RRI is flexible. Impact studies have begun to emerge, but there is no overall knowledge of the more general effects of attention to RRI as a concept or a process in the Horizon2020 programme. Recently, policy documents from the EU have adopted a slightly changed use of language towards focusing more on the terms Open Science and Open Innovation as overall framework terms.

Many countries, such as for instance Denmark, do not have a well-developed policy on RRI, although in some cases some of the content is covered through the use of other concepts, such as "Ethics" or "Scientific Social Responsibility". It is not uncommon for funding bodies to discuss how they can integrate forms of reflection and action aimed at achieving social desirability in the grant applications. Such considerations, however, also often lead to discussions about how to evaluate and assess such aspects in the peer review process.

Furthermore, there seems to be a general discrepancy between the uptake of the term RRI in some policy circles and the research community as a whole. In general, it would be most accurate to say that the awareness of RRI is uneven in scientific communities in the European countries. While some scientists have been engaged in discussions of social desirability of their research for decades, many other groups have not heard about this concept and are rather critical towards what they see as "more administrative demands" and grant application "box-ticking" which will at best have no real impact on science. It is not uncommon for scientists to comment that the entire RRI agenda seems very remote from what they do in their laboratories.

A.2.3 General trends

In addition to the activities in different areas of biotechnology mentioned above there are also trends that are more general and influencing all or most of these areas. Genome-wide analysis of DNA, RNA, protein and metabolites are already central in the field. Methodology is advancing to move omics analysis to the level of individual cells, tissues, whole organisms, populations and biological samples of soil, air, water and even the intestinal tract bio-flora. This type of analysis generates an immense amount of data that require both software, hardware and intellectual skills to handle and to extract useful information from. Bioinformatics and Systems Biology tool development and application is required for data analysis, interpretation as well as prediction and simulation of biological processes. A massive amount of data is already freely available where information has been extracted to only a limited extent. Even more data has likely been generated where availability is more restricted. Networks like Digital Life Norway (DLN) and collaborations like the EU funded PERMIDES are good examples of attempts to utilise this data for research, innovation and biotechnology based industry in Norway and in Europe.

Genome editing with the CRISPR/Cas9 technology has developed rapidly and enables the very precise genetic reprograming of many cell types. This technique has the potential to become an important tool for the treatment of many important human, livestock, poultry and fish diseases. CRISPR/Cas9 technology also has major potential in the breeding/engineering of animals, plants and microorganisms. However, the technology can also be seen to re-invigorate the standing controversies on biotechnology and its legitimacy might be a point for more heated public discussion in the future.

There is much focus today on environmental issues and an increased interest in finding ways to reduce climate gas emission, reduce and recirculate waste, and re-use man-made products. Biotechnology offers a potentially very important contribution in this process towards a more sustainable society. For example, already today biotechnology tools have contributed in many countries to improved fermentation processes and production of biofuel from organic waste. However, to further enhance these processes there is a need for a clearer national climate and environmental strategy and action plan.

A.3 Analysis of the programme portfolio and the programme's contribution

BIOTEK2021 has a distinctly industry-oriented profile, and thus, focuses on developing biotechnological innovation. Basic research is not to be supported by the programme.

BIOTEK2021 attempts to meet the national research priorities as set up in the programme's primary and secondary objectives. The primary objective for BIOTEK2021 is to generate biotechnology that contributes to value creation and innovation to solve societal challenges in a responsible manner. To achieve this objective a set of secondary objectives has been defined. These objectives enable to better measure how the primary objective has been met.

The six secondary objectives are:

- To develop the generic elements within biotechnology, thus enabling Norwegian research groups in academia and industry to compete at an international top level (i.e. Scientific excellence).
- To address the various needs and special features of each sector in a manner that activates synergies and fosters cooperation (i.e. Differentiation).
- To ensure that support is provided to areas in which biotechnology is essential for value creation and industrial development that benefits the society (i.e. Innovation).
- To ensure the responsible development of technology that addresses global societal challenges in the areas of health and sustainable food and industrial production (i.e. Societal challenges).
- To establish conditions that promote cooperation, constructive task distribution and highly focused research activity within Norwegian biotechnology research (i.e. Collaboration).
- To communicate with specified target groups to ensure that biotechnology research and development are in line with the societal needs (i.e. RRI).

In line with the national strategy, the programme has focused on four thematic sectors: 1) marine biotechnology; 2) biotechnology in agriculture; 3) medical biotechnology and 4) industrial biotechnology.

The programme has been active and flexible to find ways to achieve these objectives. For this purpose, it supports different project types. Almost half the funding has been allocated to researcher projects which are R&D projects designed to promote scientific renewal and development of disciplines and/or to generate new knowledge about issues relevant to society. The major part of the researcher projects are five large-scale, industry relevant researcher projects which focus on biotechnology as an enabling and multidisciplinary technology while only very few are traditional researcher projects. BIOTEK2021 also funds optimisation projects to support research and development of biotechnology products, processes and services that have commercial potential, and where there is a need to develop and conceptualise the technology to adapt it to commercial use. The programme has funded initiatives, like Idea Labs to bring forward new and innovative ideas in the interfaces between different disciplines and strategic initiatives as the Centre for Digital Life Norway. The programme also supports European joint calls and to a lesser extent events.

Going through the secondary objectives of the BIOTEK2021 programme, the expert group made the observations which are presented further in this section.

A.3.1 Scientific excellence

This objective has not been evaluated as such. It is not possible within the current evaluation to assess the degree of excellence based on bibliometric or other tools since most of the funded projects are still running. It can, however, be noted that there is a list of already achieved publication outputs. More so, the survey also demonstrates that a majority of respondents expect the project to lead to improvement of scientific excellence.

An indicator of scientific excellence is how well Norwegian research teams are represented in European networks. This seems to be working well, particularly due to the specific funding in BIOTEK2021 linked to the ERA-nets. Based on the data available to the Expert Group it is not clear whether funded research teams as a continuation of their projects also have received EU-funding.

In the explicit goal to foster excellence and innovation, the decision was made to setup the DLN and to allocate a third of the funding for this initiative. The strategic vision paper for this ambitious initiative describes how it should be at the forefront of interdisciplinary research in biotechnology. The objective is to create value through transdisciplinary research to *"support the integrated development of biotechnology based on disciplinary convergence rather than the development of new, stringently delimited disciplines"*. This should be done through the establishment of a national hub-node centre structure to create a *"vibrant, networked and transdisciplinary"* community.

Compared to similar efforts internationally, DLN is more ambitious in its comprehensive approach to transdisciplinarity. The strategy has been discussed with a large group of stakeholders, so it should be safe to assume that there is an overall buy-in to this ambitious strategic goal. At the same time, however, it is interesting to consider the implications of using a funding body, such as RCN, as the key driver for a change of the fundamental collaborative processes and cultures of science. Within organisational studies it is a standing discussion whether a strategic actor deliberately can change a culture or whether culture is more fundamental and hence beyond the reach of strategic actions. The expert team is not equipped to provide definite answers to this. However, it can be noted that the recommendations for the hub-node structure and the way it is implemented in the calls for DLN applications seems rather complicated. It is asking applicants to align a lot of different aspects and such demands can easily be seen as overly bureaucratic to applicants. The question is whether all these innovative and specialised goals are an enabler or a constrictor of excellence? According to RCN, excellence is not the main goal of DLN (but rather a necessary condition for funding), but the question here is meant more broadly in terms of how Norwegian research develop in the future.

Similarly, the DLN strategy puts more emphasis on law, social sciences and humanities as integrated in the network than what is usually seen in an international context. However, such an approach also demands a whole new role of social scientists and scholars in arts and humanities. Traditionally, such researchers have primarily been adopting a role of observers; but in the ambitious DLN strategy they need to become active partners and co-creators. It is not entirely clear how well-equipped they are to take on this new role.

A.3.2 Differentiation

Differentiation can be a good strategy if the point is to make sure that a smaller country has sufficient competence within all knowledge areas to utilise and benefit from technologies and knowledge created in the entire global research system. However, a sufficient knowledge level in research areas is not necessarily the same as being an innovation leader or even being technologically competitive at a global level. Often this needs investment at a different level at the same time as it also demands an infrastructural match between business structure and research excellence in the country. Such an infrastructural match cannot simply be created over a short span of years even if the investment is massive. It is instead a long-term investment (decades) of a very large kind. Differentiation can therefore be a challenge for a small economy with limited resources, and it is a common theme among research policies to talk about prioritisation in order to strengthen areas of national or regional strength.

It is an explicit objective of the programme that each sector's special needs should be met and be allocated at least 10% of the programme's portfolio. Marine biotech should be given a special place and be awarded at least 25% of the portfolio. With regard to the marine sector the goal is reached, but the other sectors are quite different from each other in terms of size in the programme portfolio. It should be noted that the agricultural biotech so far has been awarded only 7% of the funding. This, however, is not necessarily a problem as the allocation of funds is based on criteria of excellence and relevance. It is thus assumed that green biotech has been awarded funds according to the quality of the applications in this area. It might be relevant to consider whether the programme's objectives should keep the ambition of spreading the available resources over all sectors.

As an example the medical sector may be considered. The medical sector is a sector with high priority in most countries and is internationally highly competitive. So far, this sector has received most support from BIOTEK2021 (41%). Considering the lack of a strong and established business structure

in Norway for the medical sector as well as the fact that a major part of the innovative concepts and SMEs not have generated lasting economic return it can be discussed if the funding could better be used in other sectors where Norway is more competitive and has a more established business structure.

A.3.3 Innovation

BIOTEK2021 has allocated almost half of its funding to researcher projects and when examining the titles of the funded researcher projects, they all do appear to have an industry oriented profile relevant to the programme. However, it is disturbing that a small fraction of the participants may not see this profile as indicated in the answer presented in Figure 10 of the Technopolis report. Around 10% of the participants do not agree with the statement that "Increase value creation through the development of products, processes and services" was a motive for participating in the project. At the same time, almost 50% of the researcher projects do not see that the programme setup allows them to get needed help (e.g. mentor, sign-posting) for the commercialisation aspects. There are many comments among the project managers that the TTOs are not supporting development efforts enough. However, there are few critical remarks about the optimisation funding and it appears to have worked well.

The national research institutions are committed to being part of the transfer of innovative technologies for the benefit of society, and their involvement in projects may be necessary to further increase focus on the commercialisation aspects of the programme. One could look into the compatibility of the different tools (*"virkemiddelapparatet"*) to ensure that the new innovation can reach their commercial potential. However, this should be done as a separate evaluation by RCN.

It is a specific objective to increase the collaboration between businesses and research sectors. This is an obvious goal and should be applauded. The expert team notices that although some companies are partners in the large researcher projects it seems that rather few companies have received funding from the BIOTEK2021 programme, particularly when compared with the NANO2021 programme. If this is the case and not just a result of other factors or misleading reporting, this should be investigated. Since the financial analysis only shows the companies that are project managers it may be that more companies participates in projects in other ways. One important thing to consider in this context is whether Norway has a business sector and a research sector which are compatible and able to work together in the ways demanded by the programme. It is critical for a successful commercialisation of novel innovation in Norway to also consider the structure of the national business sector. Without a strong and compatible business sector able to work together with the research teams in the programme there is an increased risk of commercialisation failure or that funded projects are commercialised outside the country.

A.3.4 Societal Challenges

All researchers and businesses should address societal challenges in a responsible way. Together with the NANO2021 programme a framework for RRI has been created and it seems that particularly the researcher projects have all demanded an RRI component – something which has also been assessed by specific experts in this field. Together with other programmes a specialised call within ELSA and RRI was announced in 2014 and RRI is a central and integrated component of the DLN initiative.

There is no doubt that RCN and the BIOTEK2021 as well as the NANO2021 programme must be in the forefront internationally when it comes to the implementation of an RRI-perspective. Very often RRI is seen to be a loosely connected add-on to research programmes which lead to a "box-ticking" behaviour by applicants and hence has very little impact on actual research projects. The RRI-framework developed by RCN and particularly the DLN initiative is an inspiration for other funding bodies across the world.

In general, survey respondents also seem rather positive about the RRI components of the programme. Workshops and other events on RRI are considered positive by many and the evaluation of grant proposals about its RRI elements is seen as fair. Nevertheless, it should be noted that the general assessment process is described by many respondents as not being transparent.

technopolis_[group]

It should, however also be noted, that the RRI theme seems to have created polarisation. While many respondents are very positive, others are really very critical and see it as offensive that such an agenda suggests that scientists are not responsible by themselves. There are some descriptions in which the RRI experts and parts of the RRI is described as a clique which positions themselves to have power to decide what is "good" research and what is not. Technopolis suggests that this points to a need for better communication about the objectives and ambitions of the RRI agenda.

While this is no doubt true, it also points to a fundamental conflict about governance of science which has been particularly pronounced in the global controversies on biotechnology. The basic distinction in this conflict is whether society can and should trust science to regulate itself or whether it is necessary for society to impose regulation from the outside. The negative assessment of RRI by some of the respondents seem to be based in a fundamental value that science must be governed by scientists themselves. Such a value is not necessarily overcome by communication in the form of more information about the RRI agenda. Rather it points to a basic political discussion about whether science is and should be within democratic control. While the RCN's RRI framework is based on an integration model of the science and society relation, criticisms are based on a separation model. Subscribing to either one of these models is ultimately a political question.

One way of dealing with such a conflict is to demonstrate how the RRI agenda can be useful to science. Another is to find ways of demonstrating that the RRI agenda is not something new, but is built on the responsibilities already exercised by scientists and takes its point of departure in what scientists already do. Such an approach might seem more respectful to scientists, but on the other hand it does, of course, make it more difficult to brand DLN and similar initiatives as internationally leading and "new".

A.3.5 Collaboration

The sub-goals here are about the creation of DLN, about creating a project portfolio that contributes to cooperation, distribution of labour and concentration. Finally, there should also be support for national research schools and infrastructures. DLN has already been discussed in the "Scientific excellence" part of the report and nothing further needs to be added here. Collaboration is in general a "good thing" that can aid the generation of novel knowledge and ideas. Collaboration can also make the collaborating team a stronger entity that can reach goals that would otherwise have been impossible or at least very difficult to reach. At the same time as the benefits of collaboration is clear it may not always be a benefit when the collaboration demands of the DLN funding has indeed seemed very bureaucratic and might have hindered other forms of collaboration that did not fit into the stipulated scheme.

A.3.6 Communication

It is obvious from the annual reports and other documents that there has been a number of events and other communication activities, but the expert team did not have particular information about the impact of these activities. Such impact is also very difficult to assess. It looks as though such efforts are in line with what has been done internationally.

A.4 Conclusions and recommendations

As a general conclusion, the expert team believes that the BIOTEK2021 programme has worked well to reach its objectives. The programme has listened to the users of the programme, has had an active internal evaluation process running, shown flexibility and introduced novel funding opportunities during the period to further improve the chances of a successful programme. It is still too early to evaluate some success factors like publications, citations, patents, licensing agreements and established SMEs. The projects in the programme need more time to generate measurable results and the expert team has not considered these factors in this evaluation.

The expert team based their evaluation on the Technopolis BIOTEK2021 evaluation report together with their own experience generated over time and considered the international trends in the

biotechnology sector. Experts compiled a set of conclusions and recommendations that they believe could help to further develop the BIOTEK2021 programme.

The optimisation projects are R&D projects that have a clear industry-oriented profile fully in line with the objectives of the programme and is perhaps the project type that have received fewest critical remarks. The chances of having some of these projects to develop into something with a commercial value and meeting the many challenges in the society should be good.

Some of **the researcher projects** appear to have a somewhat reduced attention to the commercialisation aspect but the answers in the survey also indicate that this can improve if some of the funding is allocated to include some tools (e.g. mentors, sign-posting) intended for this purpose. The expert group agrees that RCN should consider including such tools to raise the focus of this aspect.

Considering Norwegian business structure. As mentioned before BIOTEK2021 has a distinctly industry-oriented profile and the primary objective for the programme has been to generate biotechnology that contributes to value creation and innovation to solve societal challenges in a responsible manner. The programme focuses on developing biotechnological innovation, and on the application of research results as a means of promoting value creation and industrial development related to solving major societal challenges in a responsible manner.

Internationally biotechnology is used for commercialisation purposes in many different areas. It can contribute to value creation from many areas of research and from many industrial areas including medicine, agriculture/forestry, veterinary science, marine resources, waste management, and many industrial processes. However, Norway has limited resources and it will be challenging to be scientific excellent in all areas of research and be successful in value creation from all areas of science. The Norwegian Research Council has to some extent recognise this and BIOTEK2021 has allocated most of its funding to medical and marine biotechnology and less to agriculture/forestry and industrial biotechnology.

Since Norway is a small country with scarce resources it is very important that policy makers together with R&D institutes look carefully to potential niches the biotechnology sector should seek to fill when making future programmes or developing products with commercial potential.

The national resources including competent capital should be sufficiently large to generate a critical mass necessary to create products and services with market potential. From an international point of view Norway does not have a very strong business structure in the biotechnology area. The expert group suggests that BIOTEK2021 should consider focusing on the areas where Norway has a special advantage and strength and preferably a national business structure to better absorb the commercial potential of the programme.

Digital Life Norway (DLN) is a large commitment made by RCN and BIOTEK2021 where about a third of the funding is invested. It is important to determine if this is funding well spent or if the investment could better be used on other activities to reach the objectives of the programme. Is the size of the DLN initiative appropriate? Could a reduced funding achieve the same commitment to the collaboration effort? What can be learned from similar national initiatives elsewhere, especially with regard to impact on research and the development of new concepts as compared to more distributed funding schemes? There are also indications that the application process may appear rather complicated. Can the procedure for including new partners and projects be simplified and made more appealing for potential applicants? The expert group has previously also raised the question whether all the innovative and specialised goals in DLN are an enabler or a constrictor of excellence. Internationally similar initiatives have not always been a success and the expert group suggests for BIOTEK2021 to thoroughly evaluate the DLN initiative.

Industry participation. Although industry representatives are involved as partners in the researcher projects the extent of industrial participation as project managers is still limited. It is not entirely clear if the industrial participation in the BIOTEK2021 projects in other positions changes the

impression of their restricted involvement. Would RCN be satisfied with the situation if their limited participation holds true?

It may be that many of the companies are putting more effort on more applied (more D than R&D) projects that in part may be funded by the BIA programme. Does the time scale of projects match those of industrial projects, which often have rather short-term milestones as compared to academic projects? However, in order to answer these questions, the whole portfolio of biotech-funded projects at RCN has to be analysed together. The expert group also suggests to RCN to evaluate ways (e.g. seminars) to help potential investors better understand the biotechnology field with its many interesting opportunities, its limitations and the risks associated with investing in projects in this field.

The RCN's BIOTEK2021 is an active team that has shown flexibility in the development of the programme to find the best methods to reach its ambitious objectives. It is the hope of the members of the Expert Group that we have been able to contribute in the further development of the programme.

Appendix B Survey questionnaires

About your project
1. To what extent are your research group's/organisation's activities
funded by the BIOTEK2021 programme based upon knowledge
developed under the predecessor FUGE programme?
Not at all To a small extent
To some extent
To a large extent
Do not know
2. Does the project include new partners (whom you never worked
with before)?
Yes, multiple new partners
Yes, one new partner
○ No

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Do not know/Not applicable
To access national research infrastructure (e.g.: databases, software for analyses and simulations measurement, clean rooms and testing facilities)	0	0	0	0	0	0
To access networks with other R&D providers (universities and institutes)	0	0	0	0	0	0
To enable recruitment of PhD candidate(s)	\bigcirc	\bigcirc	\odot	\odot	0	\bigcirc
To enable recruitment of senior researcher(s) with competence in biotechnology	0	0	0	0	0	0
To establish or strengthen cooperation with (other) research institutions (i.e. university, university college, research institute)	0	0	0	0	0	0
To establish or strengthen cooperation with companies	\bigcirc	\bigcirc	\circ	0	\bigcirc	0
To increase value creation through the development of products, processes and services	0	0	0	0	0	0
To contribute to tackling societal challenges	0	0	\circ	\circ	0	0
To access funding	\bigcirc	\bigcirc	\bigcirc	\bigcirc	0	\bigcirc
ther (Please specify)	followina	stateme	nts reflect	the dev	elopment	of your
project propos	-	otatomo			oropinone	or you.

5. To what exte	nt did the BIC	OTEK2021 pro	gramme call c	oincide with
what you wante	ed to achieve	with your rese	earch project?	
	To a small extent	To some extent	To a large extent	Do not know
Your assessement	0	\bigcirc	\odot	\bigcirc
Please explain in what way (if	any) your project idea was	s adapted to the call:		
6. What do you	imagine wou	Id have hann	ened if your pr	oiect had not
been funded by	-			oject had not
been randed by			logramme :	
Tick all that app	oly.			
The project would not ha	ve been conducted			
The project would have b	een conducted with reduc	ced scope		
The project would have t	een conducted with fewe	r partners		
The project would have be a second	een conducted but it wou	ld have taken longer		
The project would have to	een conducted in the san	ne way, but with other type o	f funding	
Not applicable/don't know	v			
7. Did you cons	ider other fu	ndina sources	2	
		nung sources	•	
If yes, please name funding so	urces considered			

About the BIOTEK2021 programme

8. Does the programme allow you to deliver your project to the initial timeplan and achieve the anticipated results?

Yes
No

If not, what can be improved?

9. How do the following statements reflect your view on the RCN's administration of the BIOTEK2021 programme?

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	Do not know/Not applicable
The RCN's calls for proposals are clear	\odot	0	\bigcirc	0	\bigcirc	0
The RCN's process for proposal assessment and selection is transparent	0	0	0	0	0	0
The RCN's assessment and selection is well motivated	0	0	0	0	\odot	0
The RCN's assessment involved necessary expertise	0	0	0	\bigcirc	\bigcirc	0
The RCN's process for project reporting (technical and financial) is efficient	0	0	0	0	0	0
The RCN's requirements for project reporting (technical and financial) are clear	\bigcirc	\circ	0	0	0	0
The RCN's support during project implementation is appropriate	\odot	0	0	0	0	0
Other (Please specify)						

10. Do you think the BIOTEK2021 programme's subjects are in line with the current developments in the biotechnology field internationally?

O Yes

() No

Please explain your answer:

11. How can the programme be scientifically improved in the future?

12. How can the programme be strategically improved in the future?

About Responsible Research and Innovation (RRI)

The BIOTEK2021 programme contributes to the increase of awareness of social, ethical and legal aspects (ELSA), health, safety and environment (HSE), and other RRI aspects i.e. cooperation with different stakeholders. All known as Responsible Research and Innovation (RRI).

13. The BIOTEK2021 programme as a whole contributes to an increase in the following

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Do not know/Not applicable
Awareness of social, ethical and legal aspects (ELSA)	0	0	0	\bigcirc	\bigcirc	0
Awareness of health, safety and environment (HSE)	\bigcirc	\bigcirc	0	\bigcirc	\bigcirc	\bigcirc
Awareness of other RRI aspects (cooperation with different stakeholders)	\bigcirc	\bigcirc	0	\bigcirc	\bigcirc	\bigcirc
Spreading the knowledge of the RRI topic	\bigcirc	\bigcirc	0	\bigcirc	\bigcirc	\bigcirc
Other (Please specify)						

14. Which activities within the programme are particularly helpful in raising the awareness of RRI?

Evaluation of the RCN's BIOTEK2021 programme - Appendices

To what ext roject:				
iojeci.	To a small extent	To some extent	To a large extent	Do not know
Strengthened your organisation's awareness of RRI	0	0	0	0
Changed your attention towards RRI	0	0	0	0
Increased spreading information about RRI within your community	\odot	\odot	\bigcirc	\bigcirc
ease explain your answer				
RI in biotechn 7. What can b 8. Did you thir and thorough re) Ja) Nej	e done to imp	prove the situa		n got a fair

Competence building
20. What do you see as the main barriers for improving the quality of biotechnology research in Norway?
21. If one of the goals of your project is to produce results that may be commercialised, does the programme setup allow you to get needed help (e.g. mentors, sign-posting etc.)?
◯ Yes
○ No
Please explain your answer. What can be improved with this regard?

Expected results of the funded project

22. Do you expect your project to achieve the following results?

from the Norwegian funding agencies to your		Disagree	nor disagree	Agree	Strongly agree	Not applicable
Additional R&D&I funding from the Norwegian funding agencies to your organisation Additional R&D&I funding	0				0	0
Additional R&D&I funding		0	0	0	0	0
from international funding agencies to your organisation	0	0	0	0	0	0
Increased industrial relevance of research conducted in your organisation	0	0	0	0	0	0
A spin-off company established in Norway	\bigcirc	0	\circ	0	\odot	\odot
A spin-off company established in another country	\bigcirc	0	0	0	0	0
Patents filed and /or licencing deals made	\bigcirc	0	\odot	0	\odot	0
Results of your project commercialised in another way nationally	\bigcirc	\circ	0	0	0	0
Results of your project commercialised in another way internationally	0	\odot	0	0	0	\odot
Other (please specify below)	\bigcirc	0	\odot	0	\bigcirc	\bigcirc
ther						
23. Do you expe esults?	ct your	project t	o achieve t	he follo	wing <u>acad</u>	emic

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Do not know / Not applicable
Scientific publication(s) co-authored with (other) Norwegian research institution	0	0	0	0	0	0
Scientific publication(s) co-authored with a research institution outside Norway	\circ	\bigcirc	0	0	0	0
Scientific publication(s) co-authored with a Norwegian company	0	\bigcirc	0	\bigcirc	0	0
Scientific publication(s) co-authored with a company outside Norway	0	0	0	\bigcirc	0	\bigcirc
Scientific publication(s) in Open Access journals	\odot	\odot	\odot	\bigcirc	\bigcirc	\circ
Increased competitiveness of your organisation nationally, i.e. compared to other Norwegian universities, university colleges and research institutes	0	0	0	0	0	0
Increased competitiveness of your organisation internationally, i.e. compared to foreign universities, university colleges and research institutes	0	0	0	0	0	0
New PhD thesis defended	0	0	0	0	\odot	\bigcirc
Access to external national research facilities, which were not accessible before	0	0	0	0	\odot	0
Access to external international research facilities, which were not accessible before	0	0	0	0	0	0
Researcher mobility (i.e. staying abroad for more than 6 month)	0	0	0	\bigcirc	0	0
Other (please specify below)	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Other						

4. To what ex		Strongly		Neither agree			Do not know /
	Not at all	disagree	Disagree	nor disagree	Agree	Strongly Agree	
Networking between actors participating in the project	0	0	0	\odot	0	\odot	0
Networking with actors within the biotechnology sector in general	0	0	0	\bigcirc	0	\bigcirc	0
Knowledge transfer between actors participating in the project	0	\odot	0	\odot	0	\odot	0
Knowledge transfer with actors within the biotechnology sector in general	0	0	0	0	0	0	0
Value creation through the development of products, processes and services	\bigcirc	\bigcirc	$^{\circ}$	\bigcirc	0	$^{\circ}$	0
Inclusion of views from actors outside the scientific community	0	0	0	0	0	0	0
Attention to the RRI aspects of the R&D activities in the project	0	\bigcirc	0	\odot	0	\bigcirc	0
Dissemination of research results to actors outside the scientific community	0	0	0	0	0	0	0

Expected outcomes of the programme

25. To what extent do you believe that the BIOTEK2021 programme as a whole contributes to ...

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Do not know / Not applicable
An increase in the quality of biotechnological research in Norway	0	0	0	0	0	0
An increase in cooperation among research environments related to biotechnology in Norway	0	0	0	0	0	0
An increase in internationalisation of research environments related to biotechnology in Norway	0	0	0	0	0	0
An increase of research mobility between research environments related to biotechnology in Norway	0	0	0	0	0	0
An increase in research in areas of critical importance for future innovation and value creation	0	0	0	0	0	0
An increase in research needed for addressing societal challenges	0	0	0	0	0	0
Meeting places for national dialogue in subjects relevant to biotechnology	0	0	0	0	0	0
Other						

Concluding remarks
26. Please add any additional comments regarding the RCN's BIOTEK2021 programme.
27. As part of this evaluation, we would like to look into a selection of funded projects as case studies. Would you like to volunteer your project as an interesting case study?
Yes
○ No
If yes, please leave your contact email address here:

Appendix C Results of the online survey

C.1 Survey methodology

They survey analysis includes results from three separate online surveys, one to project leaders, one to project partners and one to project leaders of rejected project applications:

- The project leader survey was sent to 95 individuals and yielded 61 responses (response rate: 64%)
- The project partner survey was sent to 101 individuals and yielded 26 responses (response rate: 26%)
- The survey to rejected project applicants was sent to 117 individuals and yielded 36 responses (response rate: 31%)

The mailing lists supplied by RCN are to be complete. However, certain individuals were excluded:

- Project leaders of small projects (i.e. Events, Pre-projects etc.)
- Project leaders and partners in projects that had a start date of November of 2016 or later
- Project leaders or partners that also have received funding from the BIOTEK2021 programme were placed in the respondent group of one of the surveys at random (as the surveys for both programmes were launched simultaneously) and were asked to respond based on the experiences from that programme only
- Project leaders of rejected project applications that subsequently have received funding in either NANO2021 or BIOTEK2021 were excluded from the group of "rejects" and only received the project leader survey

The three surveys contained an almost identical set of question, but the survey to project leaders, in addition, contained several questions that were not included in the other two surveys. The survey to rejected project applicants did not include questions on project implementation and expected results and impact, for obvious reasons.

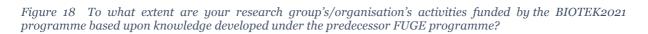
In the following presentation, responses from project leaders and partners have been aggregated where possible. Please note that some questions only were asked to project leaders and thus only contain the results of that survey. Survey responses are presented in three subgroups throughout this appendix:

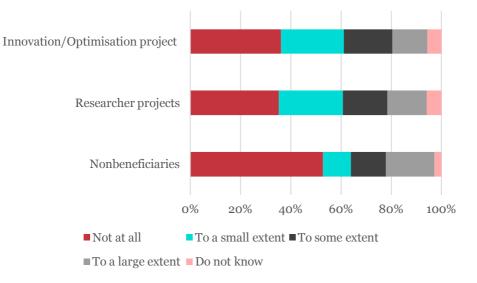
- Researcher Projects (i.e. responses from project leaders and partners in Researcher Projects, ERA-NET Projects, strategic initiatives and IdeaLab)
- Innovation/Optimisation projects (i.e. responses from project leaders and partners in Innovation Projects for the Industrial Sector (IPN) and optimisation projects)
- Non-beneficiaries (i.e. responses from project leaders of rejected project applications of all application types)

C.2 Survey results

C.2.1 Project application

BIOTEK2021 is a continuation of the Functional Genomics (FUGE) programme which was completed in 2011. The evaluation of FUGE concluded that the programme has contribute to making Norwegian biotechnology research more internationally competitive in selected areas but recommended including an increased focus on internationalisation, more cooperation and communication with the business and focus on developing research excellence in selected areas. As a result, BIOTEK2021 took into account the lessons learned from FUGE thus making the BIOTEK2021 programme a successor rather than a straight continuation of FUGE. Therefore, when looking at BIOTEK2021 from the perspective of its **links to FUGE and as a way to act on the recommendations for the future** which came out of FUGE it is useful to understand how the projects funded under BIOTEK2021 link to FUGE.





Among the organisations which participated in the survey, there is a clear difference between funded and non-funded projects. Whereas the activities of the majority of funded projects are based upon the knowledge developed under FUGE (for researcher projects 25% to a small extent, 18% to some extent and 16% to a large extent; while for innovation/optimisation projects 25% to a small extent, 19% to some extent and 14% to a large extent); it is the opposite in case of the non-funded projects where 53% of the submitted projects were not at all influenced by FUGE. A link to the FUGE programme or at least some of its activities also partially explains that most of the project ideas were in development prior to the BIOTEK2021 call (as shown in the figure below). In case of innovation/optimisation projects which took part in the survey 89% of the ideas were in development prior to the call and only 11% of projects were developed specifically for the BIOTEK2021 call. This is probably linked to the fact that before focusing on taking a project idea closer to the market or commercialisation, substantial research efforts had to be put in place meaning that the project idea was under development months if not years before the call. Whereas in case of the researcher projects 36% of the projects had ideas which were created specifically for the call. This is again not surprising given that BIOTEK2021 is set to support new research ideas as well as the further development of already existing research.

Having said all of the above, there will always be projects which are developed specifically for the call, as was pointed nicely by one of the survey respondents:

We can write many kind words but it is quite simple: researchers go where the money is and adapt to what funding agencies as for. For example, few scientists build large networks because this is perceived as particularly useful; they do it primarily because they are forced to. (This being said, the BIOTEK networks have funded very well for us!" (Funded project)

We thought that the project idea was perfectly adapted to the call, but found out that the aim of BIOTEK2021 was different than what we thought. (Rejected project)

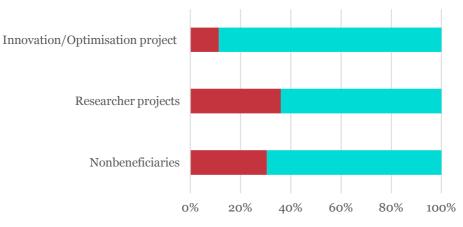


Figure 19 How do the following statements reflect the development of your project proposal?

- The project idea was created specifically for this programme's call
- The project idea was in development prior to the call

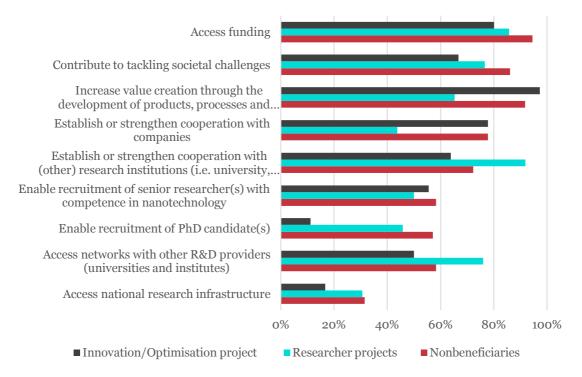
Continuation of a previously developed idea is often just one of the reasons behind organisations applying for funding from any type of programme. The survey was set to check some **other widespread reasons behind the BIOTEK2021 applicants' participation in the programme**. Here it is useful to reflect on the differences between the researcher projects and innovation/optimisation projects.

The top 3 reasons for participation in BIOTEK2021 for the researcher projects were an opportunity to establish or strengthen cooperation with a research institution (92%); access to funding (86%) and contribution to tacking societal changes (77%); and an opportunity to access networks with other R&D providers. The top 3 reasons in the innovation/optimisation projects were an opportunity to increase value creation through the development of products, processes and services (97%); access to funding (80%); an opportunity to establish or strengthen cooperation with companies (78%). A contribution to tackling societal challenges does come 4th in this list (67%) but it does have more or less same importance as establishing cooperation with research institutions (64%).

The difference between the two groups is not that surprising. Apart from funding (which is a reasonable and understandable goal for the novelty driven projects) and tacking of societal challenges (which all research groups irrespective of the key goals of their projects try to keep in mind), the other reasons shows a natural difference between the two groups. The researcher projects are focused on R&D cooperation, access to R&D networks, and recruitment of researchers and PhD candidates.

This type of funding is extremely important in order to keep continuity and competent personnel for projects that go more towards commercialisation. With the other limited postdoc grants and funding available for key technical personnel we constantly have to hire untrained personnel for limited periods, whereas here we are free to hire and prolong contracts for the trained, competent personnel required in order to deliver faster. (Funded project applicant.)

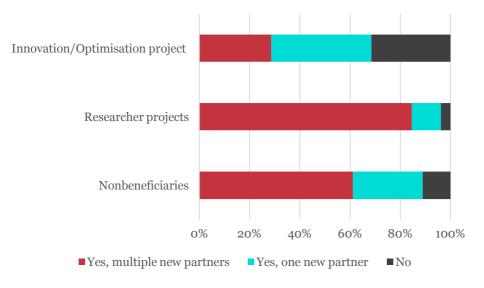
Figure 20 How do the following statements reflect your organisation's (or research consortium's / team's) rationale for participating in the project?



Note: Share of respondents who answered "strongly agree" or "agree".

The innovation/optimisation projects are aiming to develop a product, process or services, establish links to companies but do realise that this needs certain cooperation with research institutions. They are also interested in recruiting senior researchers but almost no interest in the PhD candidates. A rather big difference is seen in the main rationale for the non-funded projects to participate in the BIOTEK2021 programme. Their strongest interest was access to funding, followed by an increase of value creation through the development of products, processes and services and contribution to tackling societal challenges.

Figure 21 Does the project include new partners (whom you never worked with before)?



Note: For nonbeneficiaries the question was "Did your proposed project include new partners (whom you never worked with before)?"

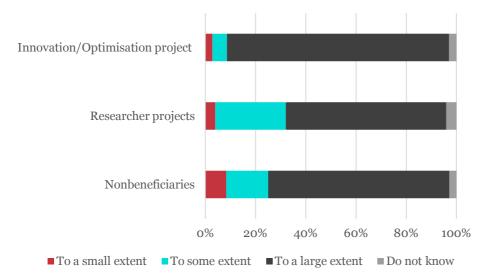
Given that cooperation with research institutions and companies was one of the strongest goals of participation in the programme, one can assume that such cooperation will be addressed first of all by including such organisations as new partners in the project. That is exactly the case in all types of projects: more than 90% of researcher projects involved multiple or one new partners and nearly 70% of innovation/optimisation projects did the same. The non-funded projects had a similar composition with researcher projects with just under 90% of them having new partners.

Knowing the reasons behind the participation of various organisations in the programme, it is crucial to reflect back on how the programme and the call the applicants participated in coincide with what the participating organisations wanted to achieve with their project. There is a subtle difference between the three respondent groups. Whereas, the majority of organisations involved in **innovation/optimisation projects** state that the programme **to a large extent** coincided with their expectations (89% of the respondents); for researcher projects the number of respondents who held the same opinion was significantly lower (64%) even though it was still the response with the overall majority. For non-beneficiaries the respondents fell somewhere in the middle with a total of 72% agreeing BIOTEK2021 coincided with what they wanted to achieve to a large extent – lower response rate than for innovation but larger than for researcher projects.

Since our research is political science and law, the programme call is not very much directed to our fields of research. The strong focus on RRI leaves the legal aspects of biotech somewhat outside the main scope of the calls. (Funded project applicant.)

The future applications absolutely warrant a BIOTEK2021 optimisation funding, but our necessary next step was somewhere in between basic research and optimization, but there are no funding mechanisms here. That would be something like UTRED, where biological hit compounds are further studied to determine if optimisation is warranted. (Funded project applicant.)

Figure 22 To what extent did the BIOTEK2021 programme call coincide with what you wanted to achieve with your research project?

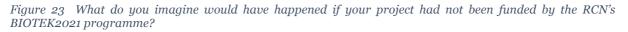


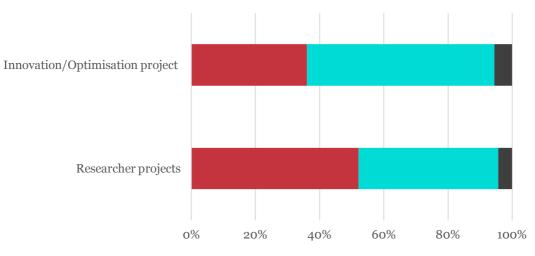
The BIOTEK2021 funding was important for the execution of the researcher projects on the level and complexity they set at the beginning. The funding was a **key turning point for the majority of funded projects**:

With funding from BIOTEK2021 we could pursue development of our basic research results towards a genetic test that might reach the clinic. Such funding is difficult to receive from other sources, so this part of our activity might not have been pursued without BIOTEK2021. (Funded project applicant.)

The project needed optimisation and proof of concept. Therefore, it was too early to apply for FONRY at the time of the BIOTEK application. (Funded project applicant.)

Only a small proportion of the projects (4% of researcher and 6% of innovation/optimisation projects) would have happened in the same way but with other type of funding. More than half of the researcher projects (which responded to the survey) stated that their project would not have happened if it had not been for the RCN funding (24 respondents believed this would have been the case). The majority of the innovation/optimisation projects felt that they would have had to reduce either the scope, the duration or the composition of their project consortium if that had not received the RCN funding (21 respondents were of such an opinion).





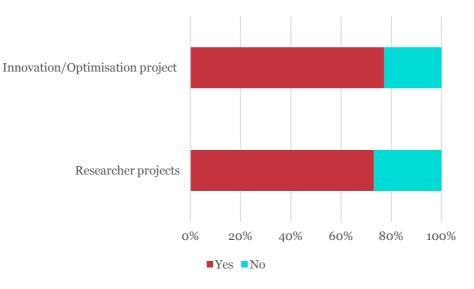
- The project would not have been conducted
- The project would have been conducted with reduced scope, fewer partners or with a longer timeframe
- The project would have been conducted in the same way, but with other type of funding

The figure below demonstrates that the majority of both researcher (73%) and innovation/optimisation (77%) projects looked for other funding sources. Among the ones mentioned were the following sources (starting from the most popular):

- EU Horizon2020
- Helse Sør Øst Innovation
- RCN's Havbruk programme
- MABIT funding early stages of various projects

- ERA-NET
- Novo Preseed
- RCN's FRIPRO
- Cancer Society
- Some internal funding or industry money
- European Research Council
- FHF
- RCN's NANO2021
- ELSA call
- GLOBVAC
- FORNY

Figure 24 Did you consider other funding sources?



When looking at what happened with the rejected projects, only one respondent said that their project is being (or have been) implemented in exactly the same way as it originally set up but with a different funding. The majority of the projects are being (or have been) taken forward with a slight modification (either in the scope, as was the case for 9 respondents, or the timeframe, as reported by 8 respondents). Of course, one needs to be more cautious with this group of rejected projects. Perhaps, having received a feedback from the BIOTEK2021 evaluators and before considering new avenues of funding their project, the team has modified the project idea itself thus leading to the changes in the partners, scope and timeframe. This is, for example, a story of one rejected application:

We are applying funding for small parts of the large proposal, trying to put those pieces together. It takes a longer time this way, the scope cannot be the same as in the original application, the work involves less partners, especially industry are difficult to keep in with the speed and funding that follows from projects not funded as a whole, but in small and separate parts. (Rejected project)

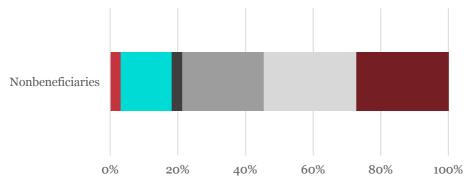
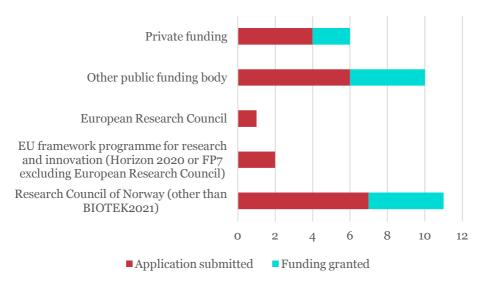


Figure 25 What happened to your research project since its rejection for funding?

- We have not applied for other external funding for the rejected research idea
- We are preparing a new project application (based on the rejected research idea) to another funding body
- We are conducting / have conducted this project exactly in the way it was originally set up but with a different type of funding
- We are conducting / have conducted the project but it will take us longer to conduct it.
- We are conducting / have conducted this project but with fewer partners
- We are conducting / have conducted this project but with a reduced scope
- We did not conduct the research project

Overall only ten respondents out of 33 admitted to either not applying for any other external funding for their rejected project (one respondent) or did not have plans to conduct the rejected research project in any capacity (nine respondents). This raises the question regarding the chosen funding alternatives for respondents with rejected projects.

Figure 26 Did you (subsequent to the application in BIOTEK2021) apply with your research project idea to other funding bodies? (Only non-beneficiaries)



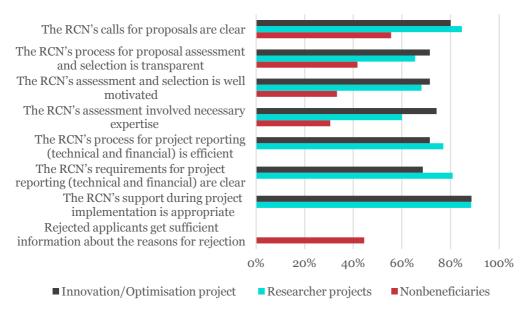
Note: Whole numbers.

The type of funding respondents with rejected projects managed to raise included other RCN programmes (in case of four projects), other public funding bodies (four projects) and private funding (two projects). Three other projects have applied (but with no luck so far) for the European Research Council and the EU Research and Innovation Programme Horizon 2020.

C.2.2 Project implementation

The views of the funded and rejected project applicants are important in understanding how the BIOTEK2021 programme is reaching its set objectives and what (and how) can be adjusted in the future. With this in mind, several questions were asked about the programme itself.





Note: Share of respondents who answered "strongly agree" or "agree".

Funded projects have been positive about the RCN's administration of the programme talking highly about the support received from RCN during the project implementation (innovation/optimisation projects at 89% and researcher projects at 88%), clarity of the calls for proposals (innovation/optimisation projects at 80% and researcher projects at 85%), clarity of requirements for project reporting (innovation/optimisation projects at 69% and researcher projects at 81%) and the process of such reporting being sufficiently efficient (innovation/optimisation projects at 71% and researcher projects at 77%).

When it comes to calls, I think there is a general tendency to be too much detailoriented, which again gives too much power to NFR bureaucrats (rather than peer review). However, in the BIOTEK programme, this has been quite good. (Funded project)

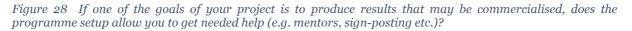
Overall very good support and processes in administration. However, seems like the evaluation process is less stringent than for other scientific programmes in RCN; I have observed a number of projects that have been awarded funding in innovation that are not scientifically sound. I have never observed anything similar for pure scientific calls, such as FRIPRO, where all awarded projects hold an extremely high quality. (Funded project)

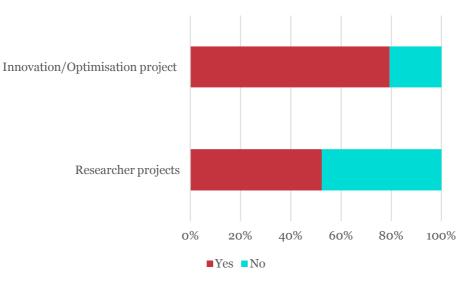
No big difference is observed between the researcher and innovation/optimisation projects. A difference between respondents strongly agreeing with the statement was only larger than 10% in the case of clarity of requirements for project reporting (innovation/optimisation projects at 69% and researcher projects at 81%) and the opinion whether RCN assessment involved the necessary expertise (innovation/optimisation projects at 74% and researcher projects at 60%). The perception of the rejected projects is, however, rather different. Only less than 50% of survey participants felt that the process of proposals' assessment and selection was transparent (42% of rejected project respondents), selection motivated (33% of rejected project respondents) and necessary expertise involved at the assessment stage (31% of rejected project respondents). A smaller proportion of the rejected applicants (compared to the funded ones) are also of the opinion that the calls for proposals are clear (56% of rejected project respondents).

The evaluations was obviously conducted and written by an expert lacking expertise in the area of the application. (Rejected project)

I cannot assess if the RCN's assessment and selection is well motivated, because it has been very unclear what the RCN's selection criteria are and, indeed, what the aims of BIOTEK2021 really are. Now, after more projects have been funded, one can guess a pattern. (Rejected project)

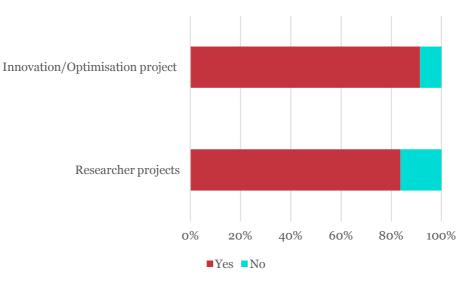
As the purpose of some of the projects was very much to think into the future and realise the commercialisation potential of the research, the applicants might have been waiting for certain support from the Council. Finding suitable mentors and being sign-posted to the relevant support are just two examples of such support. The majority of the funded projects felt that the programme setup allowed getting such needed help. Needless to say that the innovation/optimisation projects felt much stronger about that compared to the researcher projects, with 79% of the innovation/optimisation projects.



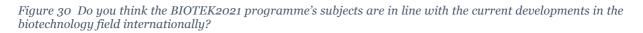


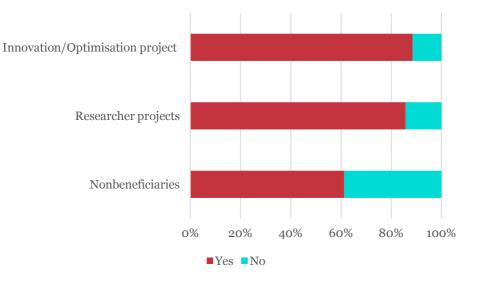
Regarding conclusion of projects the respondents were very positive regarding how the programme facilitates the delivery of funded projects keeping to the initial time plan and achieving the anticipated results. The overwhelming majority of both researcher project respondents (84%) and innovation/optimisation project respondents (91%) believed that overall BIOTEK2021 would allow them to deliver their projects to the initial time plan and achieve the anticipated results.

Figure 29 Does the programme allow you to deliver your project to the initial time plan and achieve the anticipated results?



Lastly, the respondents were asked to provide their opinion regarding the international aspect of BIOTEK2021 and for both researcher and innovation/optimisation projects the results were very positive.



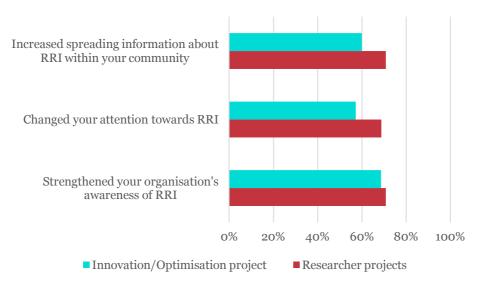


Out of all the respondents 42 working with researcher (or 86%) and 31 working with innovation/optimisation projects (or 89%) believed that BIOTEK2021 programme's subjects are in line with the current developments in the biotechnology field internationally. These results were significantly lower for the non-beneficiary category where 19 (or only 61%) held the same opinion.

C.2.3 Responsible Research and Innovation

Regarding participating in BIOTEK2021 impacting RRI while not overwhelmingly, researcher projects still reported higher levels of organisational impacts.

Figure 31 To what extent has your participation in the BIOTEK2021 funded project led to the following alternatives?

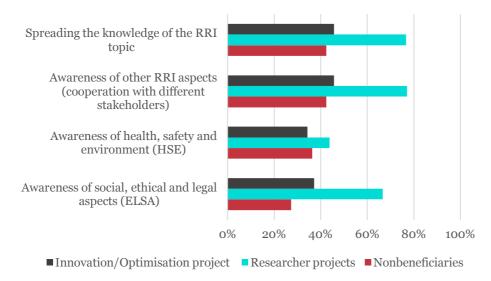


Note: Share of respondents who answered "to some extent" or "to a large extent".

The most noticeable difference is in the changed attention towards RRI which was 69% for researcher projects vs. 57% of innovation/optimisation projects. A slightly smaller difference is reported towards increased spread of information about RRI in their community (71% for researcher projects vs. 60% for innovation/optimisation projects). Only regarding whether participating in BIOTEK2021 strengthened their organisations awareness of RRI were the opinions very similar (71% for researcher projects and 69% for innovation/optimisation projects).

When taking the discourse over an increased awareness of RRI, researcher project respondents were of a significantly higher opinion regarding BIOTEK2021 impact.





Note: Share of respondents who answered "strongly agree" or "agree".

Respondents from the researcher project had the highest levels of agreement with the statements in every category, i.e. that BIOTEK2021 contributes to spreading knowledge of RRI (77%), raises

awareness of RRI aspects (77%), raises awareness of HSE (44%) and raises awareness of ELSA (67%). Out of these categories the respondents demonstrated the opinion that BIOTEK2021 has the lowest impact on raising awareness of HSE (44% for researcher projects, 34% for innovation/optimisation projects and 36% of non-beneficiaries).

The respondents were also keenly aware that RRI aspects were a necessary part of their application and would contribute to their application's success.

That inclusion of RRI aspects are required in project proposals, and are evaluated. (Funded project applicant.)

RRI has not been a topic in the project. (Funded project applicant.)

Keeping this in mind it is necessary to understand how the respondents perceived the RRI element impact on the application, whether these elements received fair and thorough review.

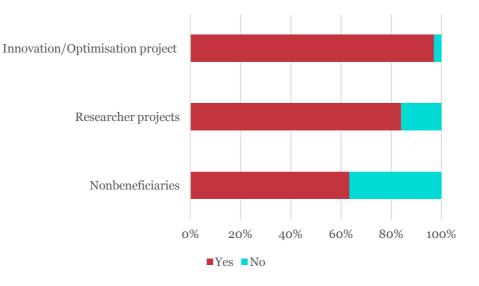
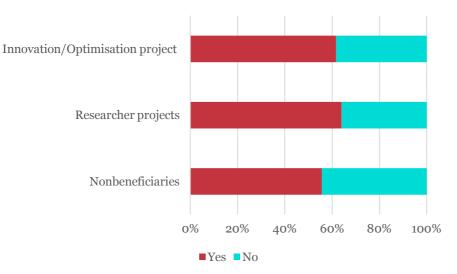


Figure 33 Did you think that the RRI element of your application got a fair and thorough review?

Perhaps unsurprisingly the largest group who believed that the RRI elements of their application did not receive a fair and thorough review were the non-beneficiaries (11 out of 30 respondents believed this). The distribution of opinion for researcher and innovation/optimisation projects is significantly more positive regarding assessment of RRI in their applications (21 out of 25 researcher project respondents felt the RRI element of your application got a fair and thorough review while this was true for 32 out of 33 innovation/optimisation project respondents).

Taking a look at a broader overview regarding the application process, the respondents submitted their opinions regarding their knowledge of how the review process worked.

Figure 34 Do you know how the process of reviewing applications submitted for the BIOTEK2021 programme's funding work?

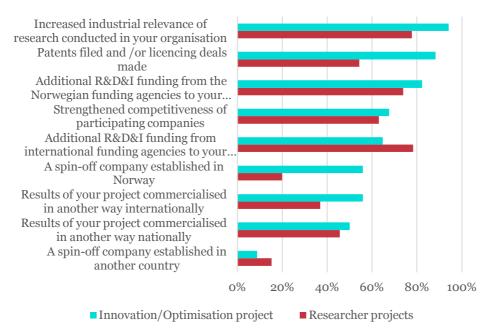


The surprising result is that there is very little difference between the three groups of respondents. The number of respondents who knew how the process of reviewing applications submitted for the BIOTEK2021 programme's funding worked was 64% for researcher projects, 62% for innovation/optimisation projects and 56% for non-beneficiaries. This demonstrates a potential weakness in the programmes design because in every respondent category over a third of the respondents were not aware of how the review process functioned.

C.2.4 Future results and impact

Regarding the future impact of the programme the respondents were asked to rate which projects results related to commercial opportunities are they most likely to achieve.

Figure 35 Do you expect your project to achieve the following results?



Note: Share of respondents who answered "strongly agree" or "agree".

For researcher projects the respondents believed that they would attract additional R&D funding from international funding agencies to their organisation (78% agreed with the statement) and that their project would lead to increased industrial relevance of research conducted in their organisation (78% agreed with the statement). These were followed closely by the notion that they would be able to attract additional R&D funding from the Norwegian funding agencies to their organisation (74% agreed). It is apparent that for researcher projects the most likely commercial outcomes in the views of the respondents were related to either increased funding opportunities or increased potential to be useful for the industry.

For innovation/optimisation projects the survey results demonstrate a viewpoint somewhat (but not that much) different to researcher projects. Firstly, the idea that the project would lead to an increased industrial relevance of research conducted in their organisation was nearly universally agreed upon (94% agreed). This was followed by the projects resulting in patents filed and/or licensing deal made (88%) which deviates from the researcher project category in that this presents results with clear commercial potential. Lastly, the innovation/optimisation project respondents also agreed that they would be able to attract additional R&D funding from the Norwegian funding agencies to their organisation (82% agreed).

An interesting point to make is that when comparing researcher projects and innovation/optimisation projects, the latter respondents believed their project would result in a spin-off in Norway to a much higher degree than researcher project respondents (56% of innovation/optimisation project respondents agreed while only 20% of research project respondents shared the same opinion). However, the potential for spin-off companies outside of Norway was given very little chance (9% of innovation/optimisation project respondents and 15% of researcher project respondents agreed to this opinion). What is interesting is that even though few respondents agreed to international spin-offs being a result, their likelihood was higher for researcher projects, as opposed to spin-offs in Norway having a higher chance for innovation/optimisation projects.

Regarding academic results there were some interesting aspects that emerged from the survey regarding national vs. international focus of the projects.

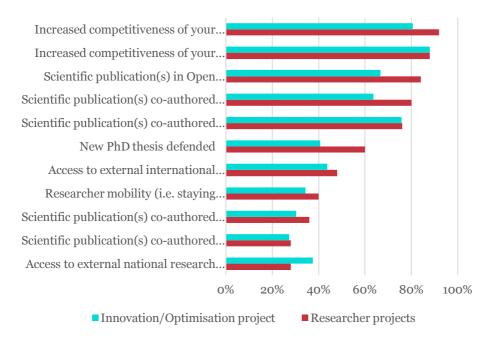


Figure 36 Do you expect your project to achieve the following academic results?

Note: Share of respondents who answered "strongly agree" or "agree".

For researcher project respondents the most likely outcomes were increased competitiveness of their organisation internationally (92% agreed), increased competitiveness of their organisation nationally (88% agreed) and scientific publication(s) in Open Access Journals (84% agreed).

In the case of innovation/optimisation projects the results for competitiveness were switched places: increased competitiveness of their organisation nationally was named first (88% agreed) while increased competitiveness of their organisation internationally (81% agreed) came second. This shows an interesting development where researcher projects are perhaps more focused on international dimension while innovation/optimisation project more so on the national dimension when carrying out their projects. This is supported by the fact that scientific publication co-authored with other Norwegian institutions came in 3rd place for innovation/optimisation projects (76% agreed) and 5th for researcher projects (76% agreed). Alternatively, researcher project respondents ranked scientific publication co-authored with research institutions outside of Norway higher at 4th place (80% agreed while only 64% of innovation/optimisation project respondents shared the same opinion). These results show an emerging divide in terms of national vs. international focus, with researcher projects in the national dimension. This can have a very simple explanation having ERA-NET projects in the researcher group.

For the next set of questions however both researcher and innovation/optimisation project respondents were of similar opinions regarding which areas and activities related to R&D saw an increase due to their projects.

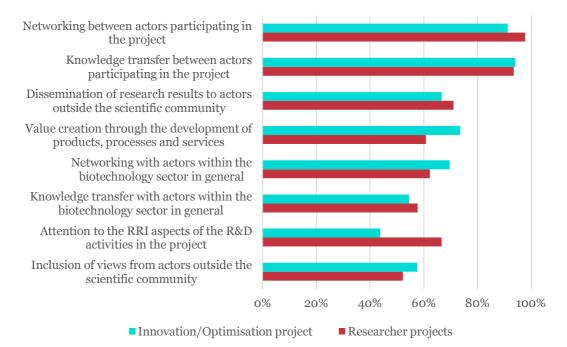


Figure 37 To what extent has your project increased the following?

Note: Share of respondents who answered "strongly agree" or "agree".

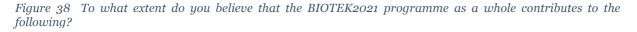
For both researcher and innovation/optimisation project respondents the most visible increases were in networking between actors participating in the project (98% researcher and 91% innovation/optimisation), and knowledge transfer between actors participating in the project (93% researcher and 94% innovation/optimisation). More significant differences emerged for later categories where researcher project respondents saw larger increases in dissemination of results to actors outside the scientific community (71%) and attention to RRI aspects to the R&D activities in the project (67%). For innovation/optimisation projects later categories were value creation through

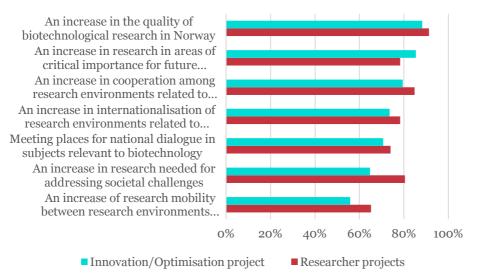
development of products, processes and services (74%) and networking with actors within the biotechnology sector in general (70%).

Finally, the respondents also rated how BIOTEK2021 programme contributed (or help contribute) to larger societal challenges.

From the point of view of the researcher project respondents the programme as a whole has the largest contribution towards an increase in the quality of biotechnological research in Norway (91% agreed), followed by an increase in cooperation among research environments related to biotechnology in Norway (85% agreed) and a tie between increase in internationalisation of research environments related to biotechnology in Norway and increase in research in areas of critical importance for future innovation and value creation (both at 78%). In the case of innovation/optimisation project respondents, the programme as a whole has the largest contribution towards an increase in the quality of biotechnological research in Norway (88% agreed), with increase in research in areas of critical importance for critical importance for future innovation and value creation being 2nd (85%) and increase in cooperation among research environments related to biotechnology in Norway coming in 3rd (79% agreed)

The lowest scores by both researcher and innovation/optimisation project respondents were given to increase of research mobility between research environments related to biotechnology in Norway (65% for research and 56% for innovation).





Note: Share of respondents who answered "strongly agree" or "agree".

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