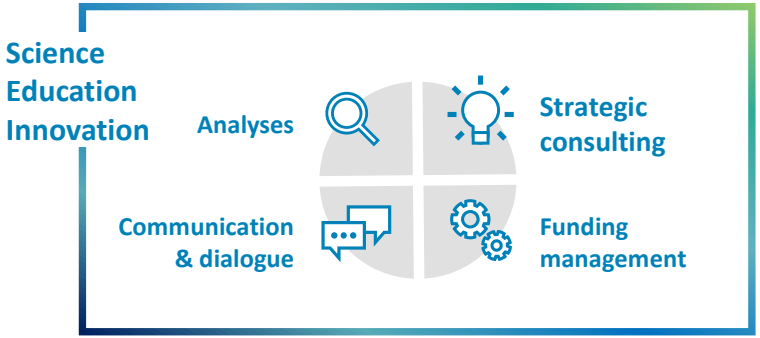
Translational Funding Measures of the Federal Ministry of Education and Research (BMBF)

Dr. Sebastian Hückesfeld, DLR Projektträger – the project management agency (DLR-PT)

DLR Projektträger

DLR Project Management Agency

- ISO certified service provider
- approx. 1,600 employees from 23 countries
- broadest range of topics of all German project management organisations



Federal and state ministries, authorities and agencies

Foundations, associations, science organisations, research institutes, educational institutions, companies

European Commission, foreign governmental agencies

Federal Ministry of Labour and Social Affairs

Federal Ministry of Education and Research

Federal Ministry of Health

Federal Ministry for the Environment, Nature Conservation and Nuclear Safety

Federal Ministry for Economic Affairs and Climate Action

European Commission

Federal Agency for Nature Conservation

Ministry of Culture and Science of the State of North Rhine-Westphalia

BADEN-WÜRTTEMBERG STIFTUNG

Gemeinsamer Bundesausschuss

DZHK DEUTSCHES ZENTRUM FÜR HERZ-KREISLAUF-FORSCHUNG E.V.

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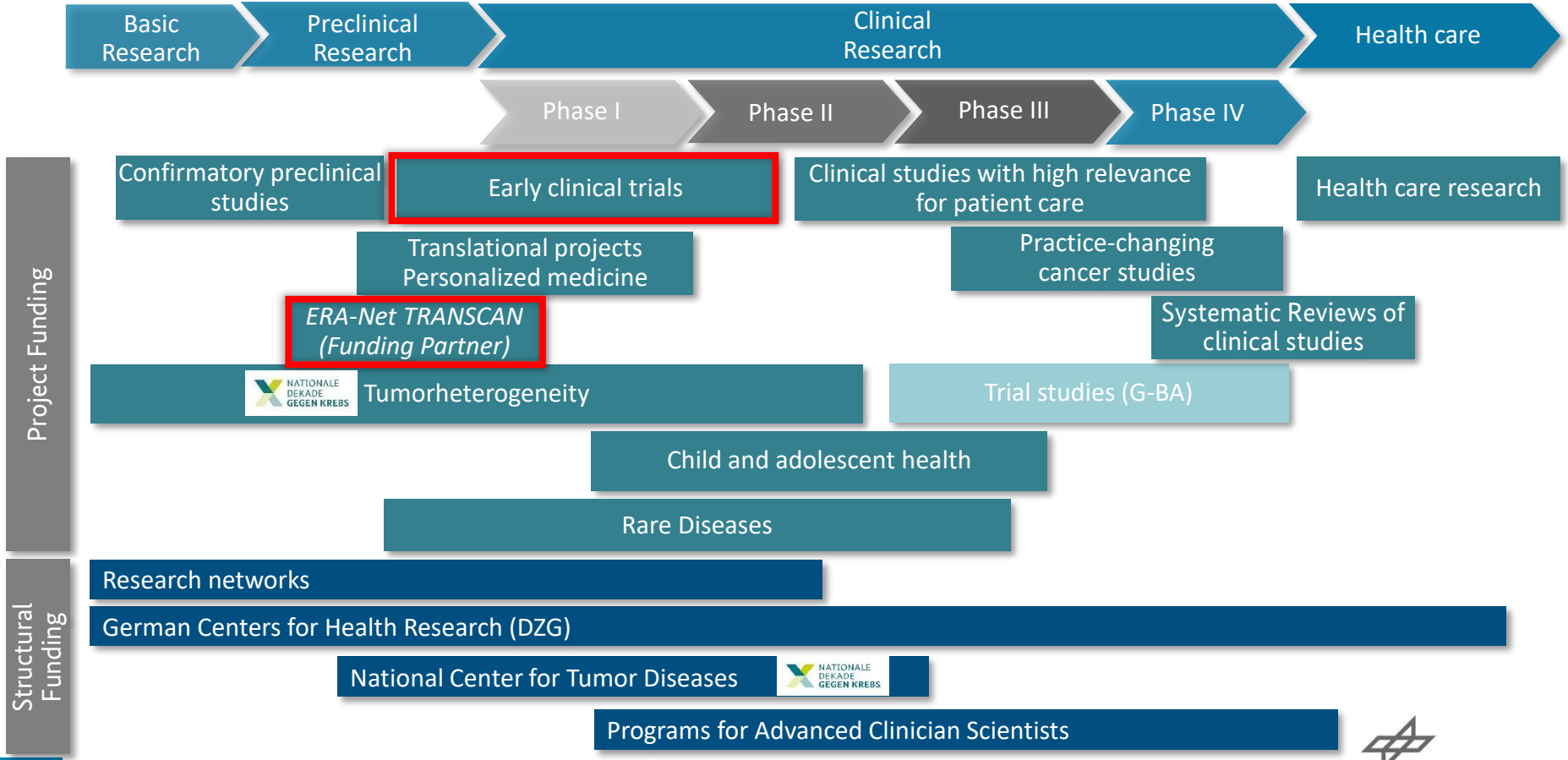
Framework Program Health Research of the Federal Government

- Promoting academic and non-academic research institutions
- Building a bridge in translation from preclinical research through clinical trials to patient care
- Strengthening investigator initiated clinical trials, where there is no direct commercial interest, through public funding and overcoming hurdles in the value chain
- Strengthening clinical expertise in Germany for successful transfer to care.

Clinical Research in the Translational Chain



DLR Projektträger

Funding measure „early clinical trials“

Aims

- Overcome existing barriers in the translational chain
- Strengthen investigator-initiated trials (IIT) in early phases
- Advance new drug applications
- Support promising new therapeutic approaches

Bildquelle

Module 1: repurposing

An already known drug is to be investigated to see if it can be used for an indication for which it is not approved.

Modul 2: new therapeutic approaches

Planning and execution of studies (clinical development) as well as, if necessary, additional work required for the manufacture of investigational medicinal products in accordance with Good Manufacturing Practice (GMP) and pharmacological-toxicological tests (preclinical research).

Funding measure „early clinical trials“

Requirements

- Trials have to be investigator initiated
- For module 2: preclinical pharmacokinetics and toxicity tests can be funded in addition to the study
- Funding period:
  - Module 1 (repurposing): 3 years
  - Module 2 (new therapies): Trial 3 years. Necessary preclinics up 3 years in addition.
- No funding if companies have direct commercial interest in the results. However, companies can be involved as collaborative partners to foster translation of a product into clinical routine.

Not being funded

- Clinical trials from phase IIb on;
- Surgical methods and radiotherapies;
- Psychological treatment methods;
- Animal model development;
- Individual healing attempts;
- Development of specific assays or test systems;
- Early clinical studies with conventional small chemical molecules in Module 2.

Funding measure „ early clinical trials“

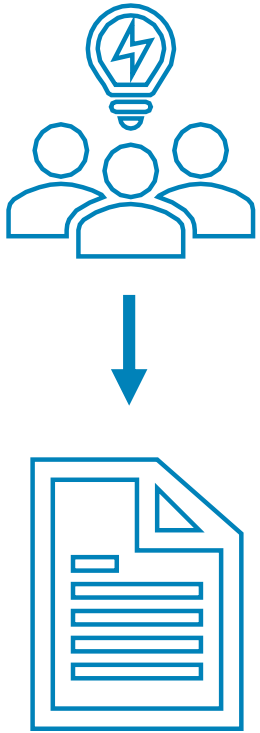
Review criteria

- Fulfillment of the objective of the call and the call requirements
- Patients or their representatives should be actively involved in study planning and implementation
- Relevance of the research question for the German health care system
- Quality and robustness of preclinical work
- Scientific and methodological quality
- Implementation of results in health care practice (holistic planning of economic feasibility)

To be considered when applying for a grant…

Biometry/Statistics

- Adequate biostatistical elaboration of the trial (signature of biometrician is mandatory)
- Adequate methodological aspects of the study design. Active involvement of biostatistical expertise when writing the proposal
- Use of new study designs especially for early clinical trials. For example, the "3+3 dose escalation design" widely used in academia is no longer considered standard in industry



KKS / CRO

- Knowledge about regulatory aspects
- Adequate estimation of timelines for chemistry, manufacturing and controls (CMC)
- Help in creating realistic development plans and logistics
- Encourage applicants to involve appropriate experts specialized in commercialization and to prepare already in this funding period possible follow-up options after successful completion of the proposed study.

To be considered when applying for a grant…

Industry

- Experience and expertise for further (commercial) development of the approaches.
- Awareness of the competing work in industry.
- Involving academic technology transfer units could also strengthen the applications in this regard.
- Clear rules on how applicants can interact with companies in this initiative are layed down in the call text.
- Possible follow-up options after successful completion of the proposed study.

ERA-NET TRANSCAN

ERA-NET: Sustained collaboration of national and regional programmes in cancer research

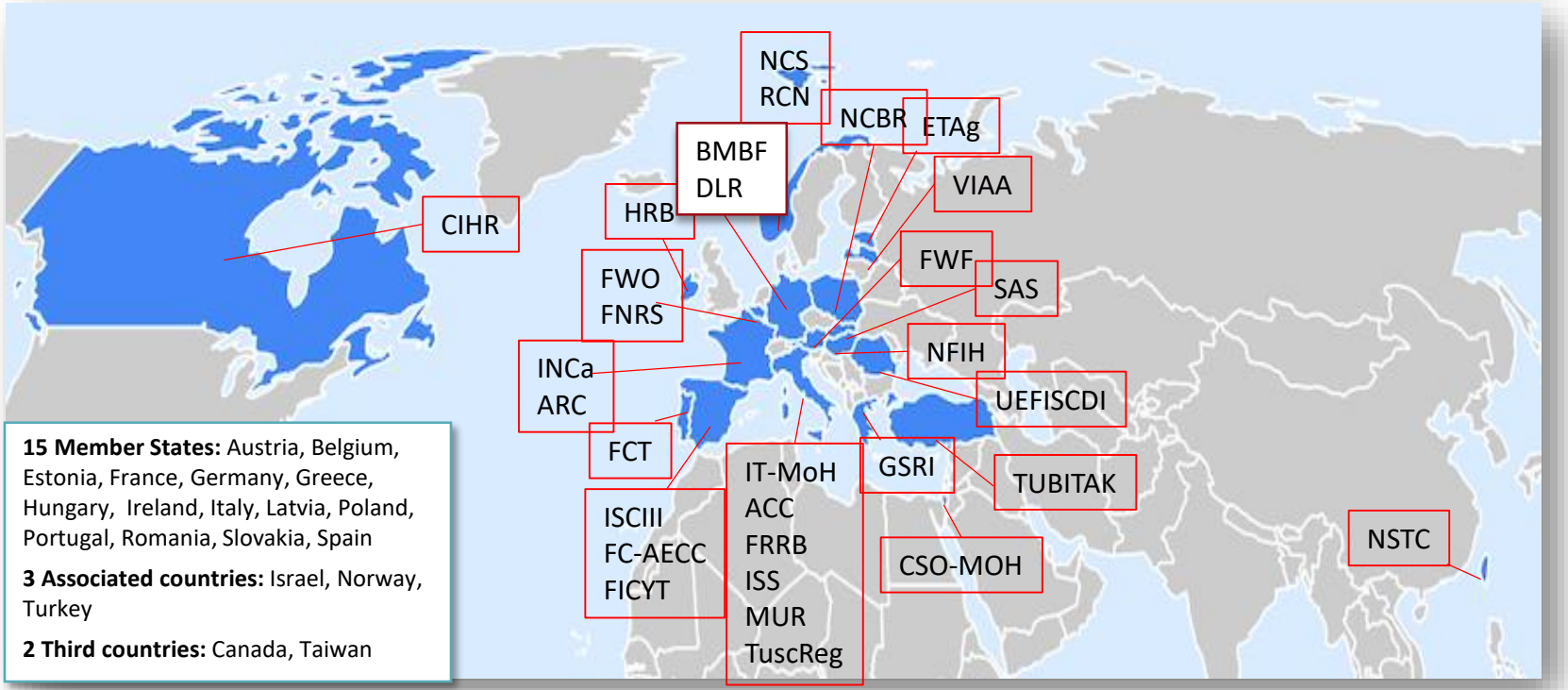
Funded by the European Union's Horizon 2020 Research and Innovation programme

5 years

…is a collaborative network of (public and private, national and regional) ministries, funding agencies and research councils with programmes in translational cancer research

- ✓ The goal is to coordinate national and regional funding programmes for research in the area of translational cancer research
- ✓ The challenge is to promote a transnational collaborative approach between scientific teams in demanding areas of translational cancer research
- ✓ To avoid the duplication of efforts by ensuring a more efficient use of available resources
- ✓ To produce significant results of higher quality and impact

31 Partners from 20 countries



15 Member States: Austria, Belgium, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Poland, Portugal, Romania, Slovakia, Spain

3 Associated countries: Israel, Norway, Turkey

2 Third countries: Canada, Taiwan

TRANSCAN-3: Sustained collaboration of national and regional programmes in cancer research (2021 – 2026)

- **First co-funded call: JTC 2021 (closed call)**:
  Next generation cancer immunotherapy: targeting the tumour microenvironment

- **Second call: JTC 2022 (closed call)**:
  Novel translational approaches to tackle the challenges of hard-to-treat cancers from early diagnosis to therapy

- **Third call: JTC 2023 – <u>open for application of proposals till July 21st 2023</u>**
  Translational research on cancer epigenetics

- **Fourth call: JTC 2024 - planned for 2024**
  TOPIC to be decided

Key aspects for grant applications

- BMBF Funding volume for each call: 3 Mio. €
- For the current call on epigenetics: 300.000 € total /project for German partners
- Project duration: max. 3 years

Requirements

- Academic research groups,
  Clinical/public health sector research groups,
  Enterprise's research groups, with particular emphasis on small and medium-sized enterprises.
- Each consortium must involve a minimum of 3 and a maximum of 6 partners, coming from at least 3 different countries. Maximum 2 research groups from one country.
- Each consortium must involve at least one basic or preclinical research team and one clinical team.
- Only transnational projects with a focus on translational cancer research will be funded.
- Optional: capacity building acitivties (investigator exchanges, short term training of scientists, training in workshops etc.) can be funded

Thank you very much for your attention!

Any ?

Links to

BMBF Health Research

BMBF Early clinical trials

BMBF Advanced clinician scientists

EU TRANSCAN

DLR Projektträger