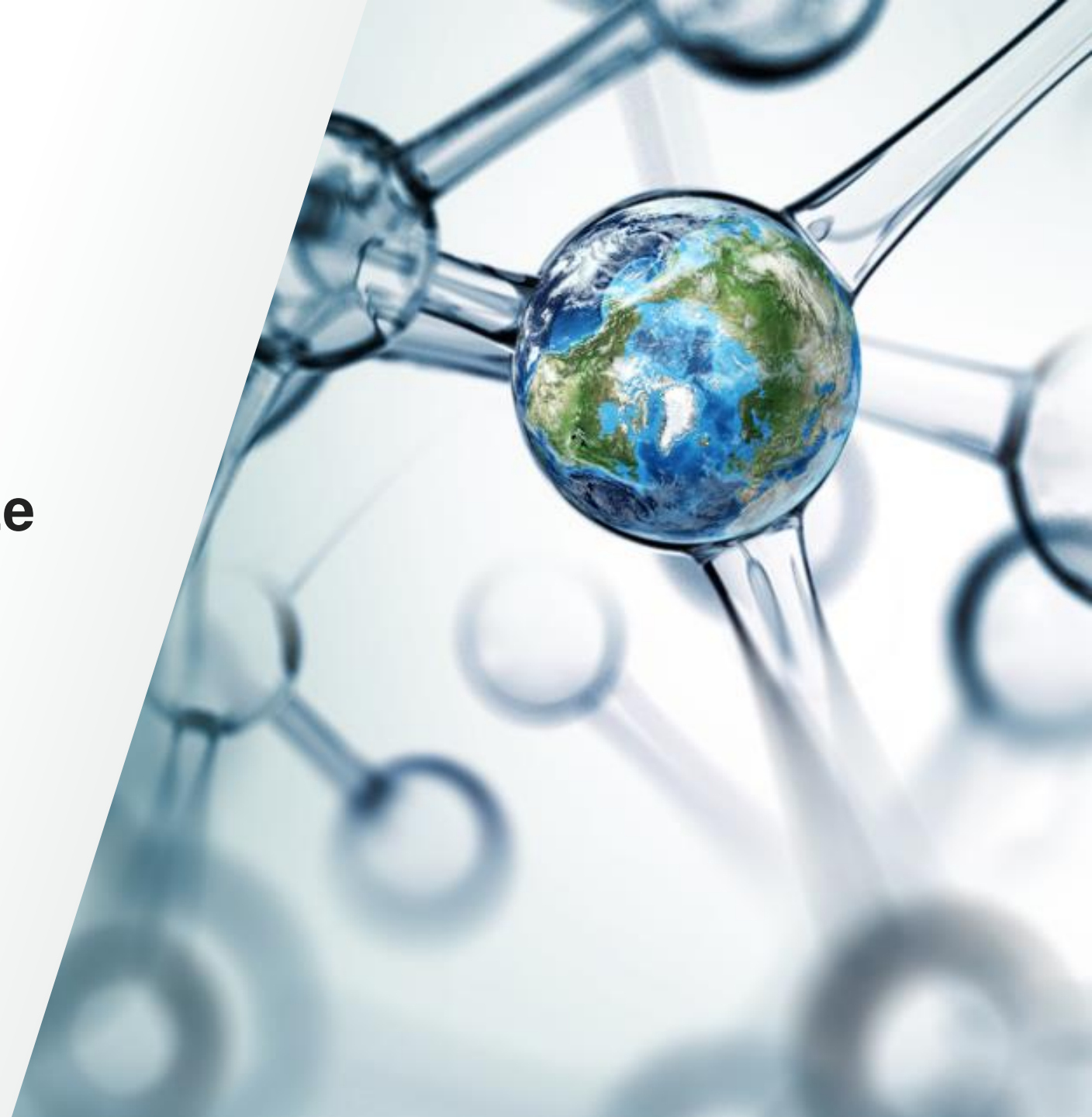
Public private partnerships – a strong way forward to maximize impact

Erik Steinfelder
Biobank Market Development Director
December 8th 2020



The world leader in serving science

Achievements in Biobanking

Building, learning, sharing expertise

Biobanking in the Early Days…

Leading biobanks were there

- UK Biobank
- Biobank Graz
- China Kadoorie Biobank

Lively discussions

- Biobank or Biorepository?
- What do you mean with quality?
- You are the freezer guys, right?

Connecting

- ISBER/ ESBB / BBMRI ERIC meetings and best practices
- National initiatives
- Patient Engagement

Shifted from sample storage to service provider.

Quality of the Samples

- **ISO 20387**
  - Available since October 2018
  - First steps towards standardization

- **High quality and reliable storage conditions**
  - Main reasons for researchers to use biobank
  - German Survey, December 2019[1]

Guidance available on best cold storage conditions per matrix.

Data provenance guidelines are currently worked on.

BBMRI-ERIC Colorectal cancer Cohort; blueprint.

[1] Source: https://www.liebertpub.com/doi/pdf/10.1089/bio.2019.0060
[2] Source: Adopt BBMRI-ERIC, D. 2.7 Patient related data for CRC Samples

Communication

Misunderstanding on both sides

- Product development and market access requires access to samples
- Not a research question – no access
- Complex access procedures around legal and ethical questions, creating timing challenges

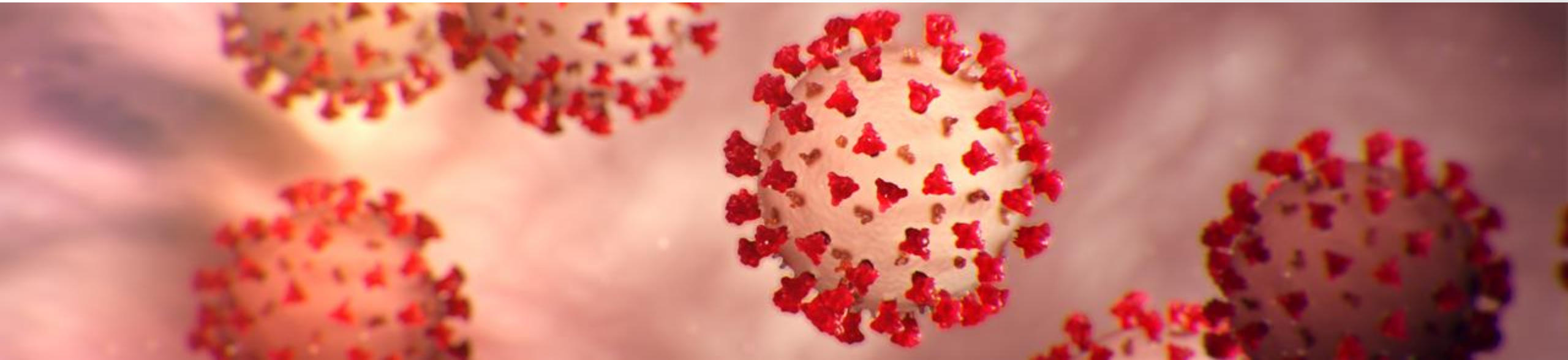
Opportunities ahead

Preparing for the next decade

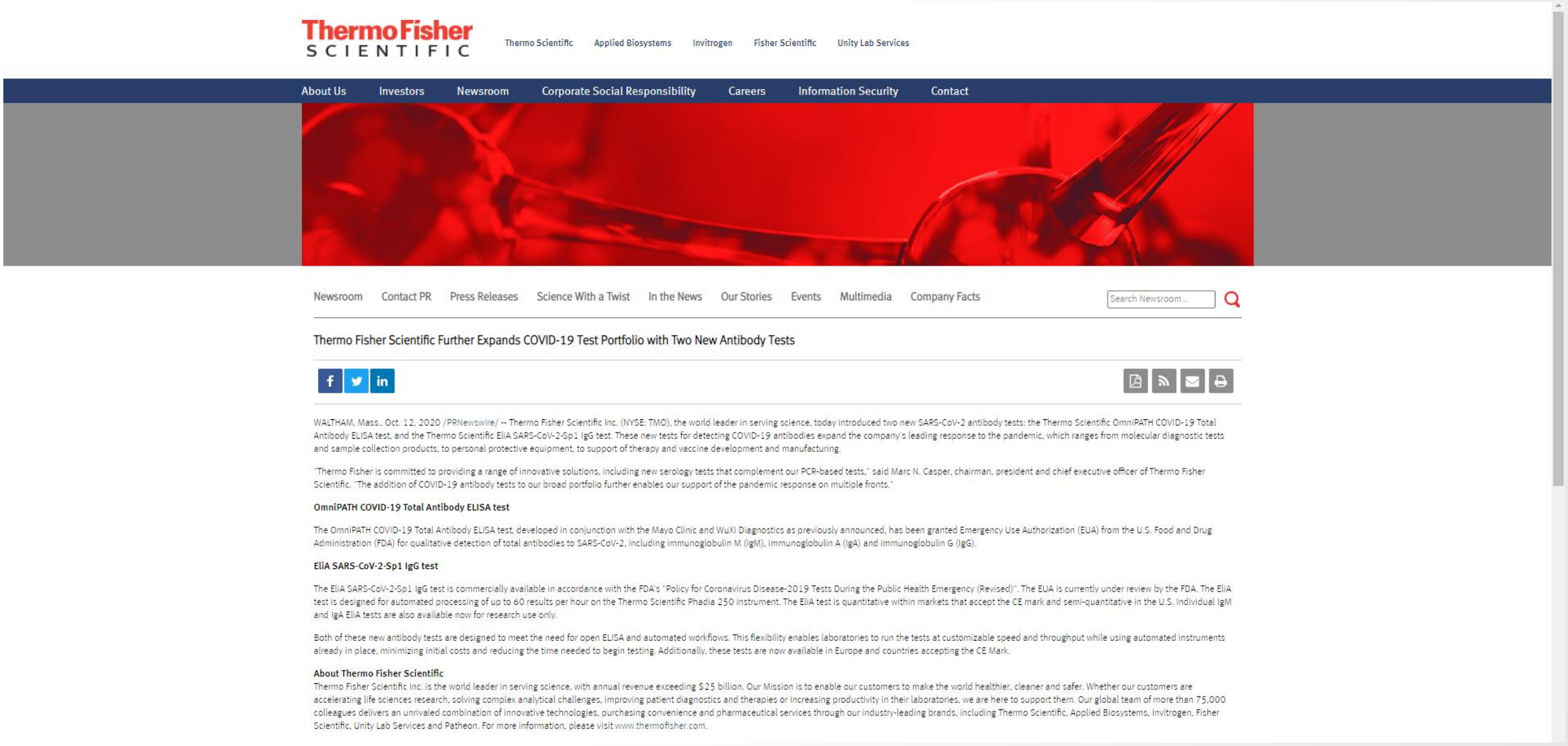
What is Needed to Support Research During COVID -19

Positive samples including associated clinical data

- **Confirmed positive samples**
  - Treatment protocol (including type of drugs used)
  - Disease severity, duration and outcome
  - Clinical symptoms (fever, dry cough, shortness of breath etc.)
- **Samples from healthy people**
  - Taken in period before pandemic
  - Majority of requests is for serum or plasma
- **Global catalogue available**
  - Joined effort of BBMRI-ERIC and ISBER



Expansion COVID-19 test



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Thermo Fisher Scientific Further Expands COVID-19 Test Portfolio with Two New Antibody Tests

WALTHAM, Mass., Oct. 12, 2020 /PRNewswire/ -- Thermo Fisher Scientific Inc. (NYSE: TMO), the world leader in serving science, today introduced two new SARS-CoV-2 antibody tests: the Thermo Scientific OmniPATH COVID-19 Total Antibody ELISA test, and the Thermo Scientific EliA SARS-CoV-2-Sp1 IgG test. These new tests for detecting COVID-19 antibodies expand the company's leading response to the pandemic, which ranges from molecular diagnostic tests and sample collection products, to personal protective equipment, to support of therapy and vaccine development and manufacturing.

"Thermo Fisher is committed to providing a range of innovative solutions, including new serology tests that complement our PCR-based tests," said Marc N. Casper, chairman, president and chief executive officer of Thermo Fisher Scientific. "The addition of COVID-19 antibody tests to our broad portfolio further enables our support of the pandemic response on multiple fronts."

OmniPATH COVID-19 Total Antibody ELISA test

The OmniPATH COVID-19 Total Antibody ELISA test, developed in conjunction with the Mayo Clinic and WuXi Diagnostics as previously announced, has been granted Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for qualitative detection of total antibodies to SARS-CoV-2, including immunoglobulin M (IgM), immunoglobulin A (IgA) and immunoglobulin G (IgG).

EliA SARS-CoV-2-Sp1 IgG test

The EliA SARS-CoV-2-Sp1 IgG test is commercially available in accordance with the FDA's "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)". The EUA is currently under review by the FDA. The EliA test is designed for automated processing of up to 60 results per hour on the Thermo Scientific Phadia 250 instrument. The EliA test is quantitative within markets that accept the CE mark and semi-quantitative in the U.S. Individual IgM and IgA EliA tests are also available now for research use only.

Both of these new antibody tests are designed to meet the need for open ELISA and automated workflows. This flexibility enables laboratories to run the tests at customizable speed and throughput while using automated instruments already in place, minimizing initial costs and reducing the time needed to begin testing. Additionally, these tests are now available in Europe and countries accepting the CE Mark.

About Thermo Fisher Scientific

Thermo Fisher Scientific Inc. is the world leader in serving science, with annual revenue exceeding $25 billion. Our Mission is to enable our customers to make the world healthier, cleaner and safer. Whether our customers are accelerating life sciences research, solving complex analytical challenges, improving patient diagnostics and therapies or increasing productivity in their laboratories, we are here to support them. Our global team of more than 75,000 colleagues delivers an unrivaled combination of innovative technologies, purchasing convenience and pharmaceutical services through our industry-leading brands, including Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific, Unity Lab Services and Patheon. For more information, please visit www.thermofisher.com.

Successful public private partnerships

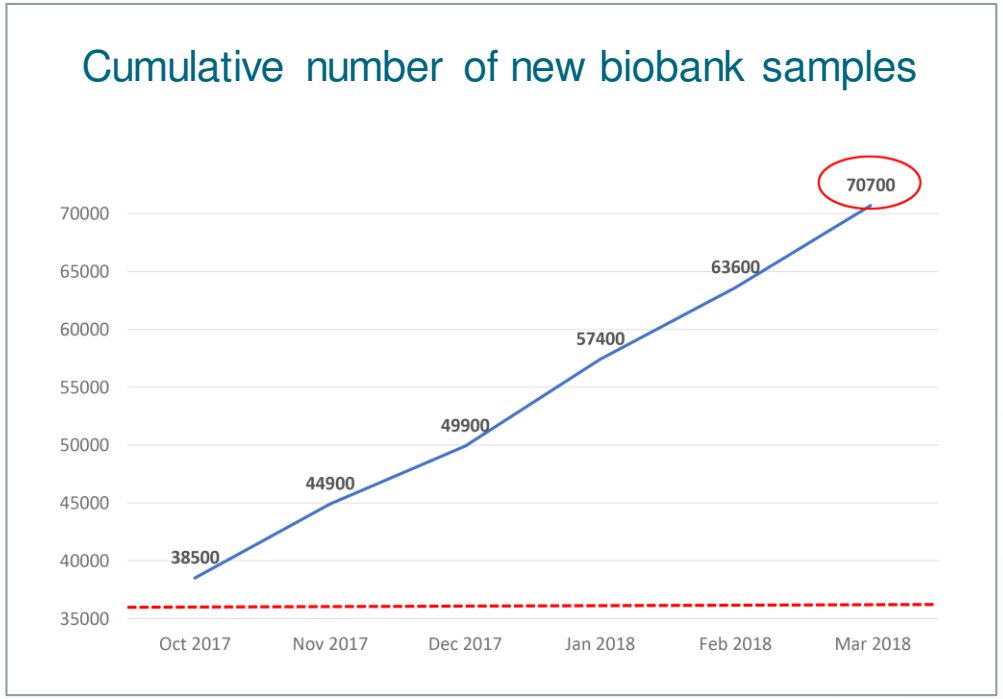
Project Conception

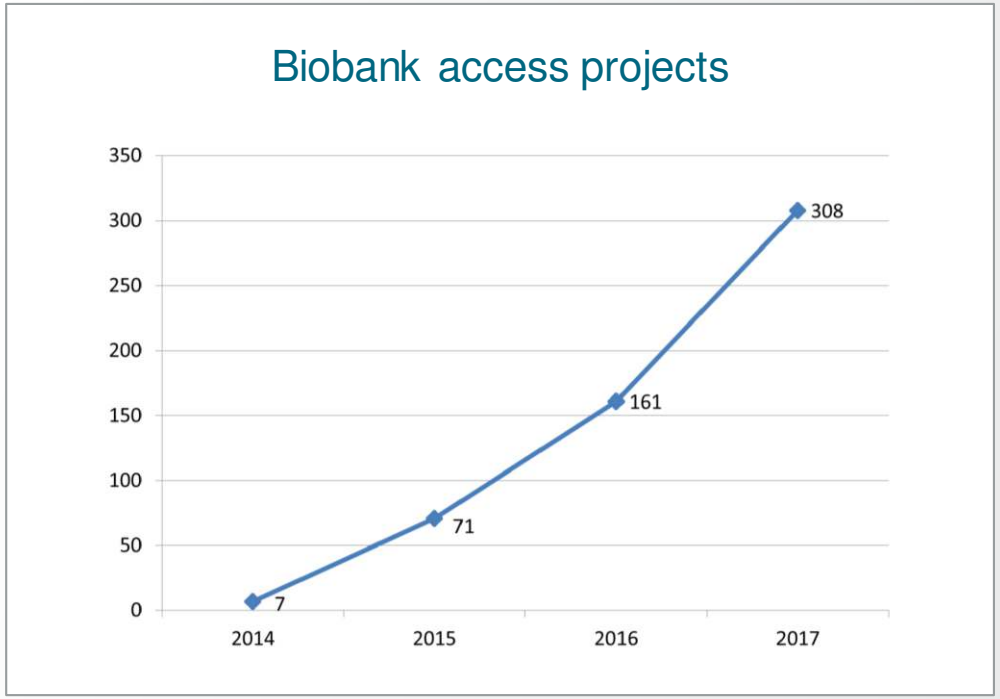
- “The main goal of ConcePTION is to establish a trusted ecosystem that can efficiently, systematically, and in an ethically responsible manner, generate and disseminate reliable evidence-based information regarding effects of medications used during pregnancy and breastfeeding to women and their healthcare providers. This will be achieved by generating, cataloguing, linking, collecting and analyzing data from pharmacovigilance, modelling, routine healthcare, breastmilk samples through a large network”.
- April 2019 - March 2024
- Budget 28.7M € (15M EU / 13.7M EFPIA)

Source: https://www.imi-conception.eu/description/, retrieved 27 August 2020

FinnGen – Increasing Use of Collections

FinnGen Project has boosted collecting new blood samples for biobanks





Auria Biobank

- **46%** industry-driven biobank studies
- **54%** academic research

THL Biobank

- **17%** industry-driven biobank studies
- **83%** academic research

Source: Adopt BBMRI-ERIC. D. 2.6 Perfomance Indicators for biobanks, retrieved 27 August 2020

EU Mission on Cancer

- **Target by 2030**
  - more than 3 million more lives saved, living longer and better, achieve a thorough understanding of cancer, improve prevention, improve diagnosis and treatment, support the quality of life of all people exposed to cancer, and ensure equitable access to the above across Europe.

- **Mission Board**
  - 15 members of which 3 are involved in biobanking community, 1 industry - and 1 patient representative.

Source: https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme/mission-area-cancer_en

ISBER 2020 Poster

Qualifiers and winners in a competitive environment

Order Qualifier:

Those criteria that an organization must meet for a customer to even consider it as a possible supplier

Order Winner:

Those criteria that win the order

Source: https://lnkd.in/dyHamch

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Thank you

I look forward to meeting you!