



National Day
•
Germany's Way
Towards Excellence in Biobanking

TMF – 12 Years a Platform for Biobanking in Germany

Prof. Dr. Michael Krawczak

Chairman of the Board of Directors TMF

- federal system (16 states)
 - many responsibilities (e.g. data protection) at state level
 - 52 ethics committees
 - relevant legislation power at state level (e.g. data protection, public hospitals)
 - funding of research at federal level, but funding of infrastructure at state level
- Federal Ministry of Health - Federal Ministry of Research
- multiple players (35 universities with medical faculties, several non-university research organizations such as Helmholtz, Max Planck, Fraunhofer and Leibniz)
- no powerful central institutions at federal level (exc. Robert Koch Institute and a few others)



- non-profit umbrella organization for academic research consortia and institutions
- established by the Federal Ministry for Education and Research (BMBF) in 1999
- funded by three federal ministries: BMBF (Education & Research), BMG (Health), BMWT (Economy & Technology)
- supported by several funding bodies (e.g. DFG)
- engaged in EU-funded projects (FP7, ESFRI, Innovative Medicine Initiative)



“TMF serves as an interdisciplinary platform for the exchange of expertise with an aim to improve the infrastructural framework of clinical, epidemiological and translational research in Germany.”

At the cutting edge.
TMF: An integrated platform for the
medical research community.

A collage of black and white photographs showing various research activities: a man speaking at a conference, a woman looking at a laptop, a group of people in a meeting, and a man pointing at a screen.

TMF – Technology, Methods, and Infrastructure
for Networked Medical Research

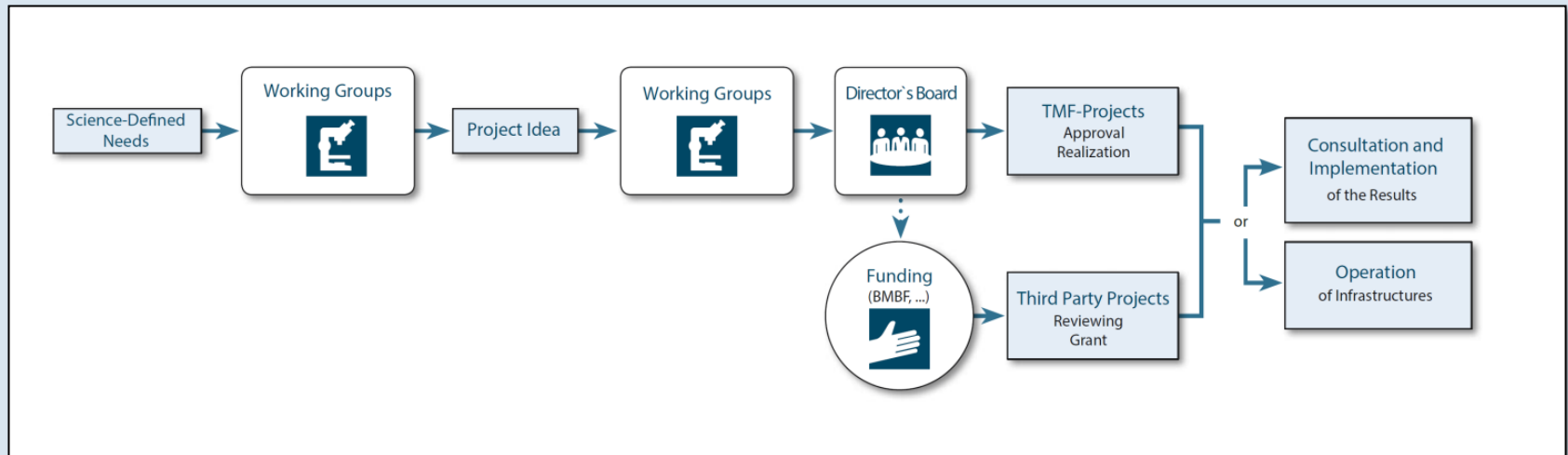
The TMF logo, featuring the letters 'T' and 'MF' inside a circular graphic.

Synergy, quality & standards – shared solutions for health



- German Centers for Health Research
 - Integrated Research & Care Centers
 - The National Cohort
 - Competence Networks in Medicine
 - Networks for Rare Diseases
 - Zoonosis Research Networks
 - Coordinating Centers for Clinical Trial
 - cBMBs
- ... and many more

Solve Researcher-Identified Problems!



- legal and ethical frameworks
- quality management and controlling
- linkage of research and health care
- standards and terminology
- IT infrastructure for clinical research

Selected solutions and products

- harmonized SOPs for clinical trials
- data protection concepts (consented by all local authorities in Germany)
- pseudonymization software for clinical research and biobanking
- approved guidelines for patient consent (+ checklists)
- severe adverse events (SAE) reporting software
- peer-reviewed publications and TMF book series
- TMF project and workshop results

**Open access and free of charge for the
academic community !**

National infrastructures

- National Research Platform for Zoonoses (since 2009)
- German Biobank Registry (since 2012)
- Registry of Registers (upcoming)
- Partner of EHR4CR Institute, CDISC, BBMRI-ERIC etc.

Involvement in standardization and knowledge-transfer

- Member and partner of several international consortia



TMF – Working Groups

- Biobanking
- Data Protection
- IT Infrastructure and QM
(incl. e-Health and Telemedicine)
- Management of Clinical Studies
- Medical Technology
- Molecular Medicine
- Zoonoses Research
- Network Management
- Science Communication



TMF and Biobanking: History

- 2003 TMF survey among Competence Networks in Medical Research identifies "biobanking" as a topic of major interest.
- 2003 establishment of TMF working group on biobanking (AG BMB); initial proposal of a framework project on biobanks
- 2006 proposal of a German biobank register
- 2012 development of a concept for a national biobank platform, in response to a BMBF call
- 2013 partner of the German Biobank Node to BBMRI- ERIC, in response to a BMBF call
- 2015 LoI for Empowerment of German Biobanks for Europe, in response to a BMBF call

48 working group meetings in 12 years



- exchange of experience
- counselling
- project work
- provision of guidelines, SOPs, generic texts etc.

2004-2006

project "Legal and Organization Framework of Biobanks in Germany"



TP1: Legal Framework (German book, English publication)

TP2: Data Protection (German book and English publication in preparation)

TP3: Patient Consent (German book, online wizard)

TP4: Quality Management (German book)

2006-2008

project "Collaborative Legal Framework of European Biobanks" (German and English generic text, English publication)

2008-2009

IT Support of biobanks (WP3 of the TMF IT Strategy Project)

- 2005 commentary on the draft of a German Gene Diagnostic Act (GenDG), for BMBF
- 2005-2006 opinion report to the Office of Technology Assessment at the German Bundestag (TAB), survey of biobanks (data protection, ELISI, IT)
- 2008 commentary on the OECD Guidelines on biobanking
- 2009 commentary on the GenDG, jointly with NGFN
- 2011 symposium on "Biobanks in Human Medicine", jointly with German Ethics Council
- 2011/12 commentary on multiple proposals for a German Biobank Act (all rejected in 03/12)
- 2014/15 commentary on EU Data Protection Directive and on WMA Declaration on Biobanking
- 2015 opinion report for TAB at the German Bundestag on "Big Data and Data Mining"

Giving a voice to science: the EU Data Protection Directive

endorsed by 45 science organizations

TMF – Technology, Methods, and Infrastructure for Networked Medical Research

Synergy, quality & standards – shared solutions for health

Comment

on the draft by the European Parliament regarding A regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation, referred to hereinafter as the GDPR)

taking into account the draft by the European Commission

[ENGLISH TRANSLATION]

Comment by

TMF – Technologie- und Methodenplattform für die vernetzte medizinische Forschung e.V.

TMF – Technology, Methods, and Infrastructure for Networked Medical Research

in conjunction with the

Netzwerk der Koordinierungszentren für Klinische Studien (KKS-Netzwerk)

Network of the Coordinating Centres for Clinical Trials

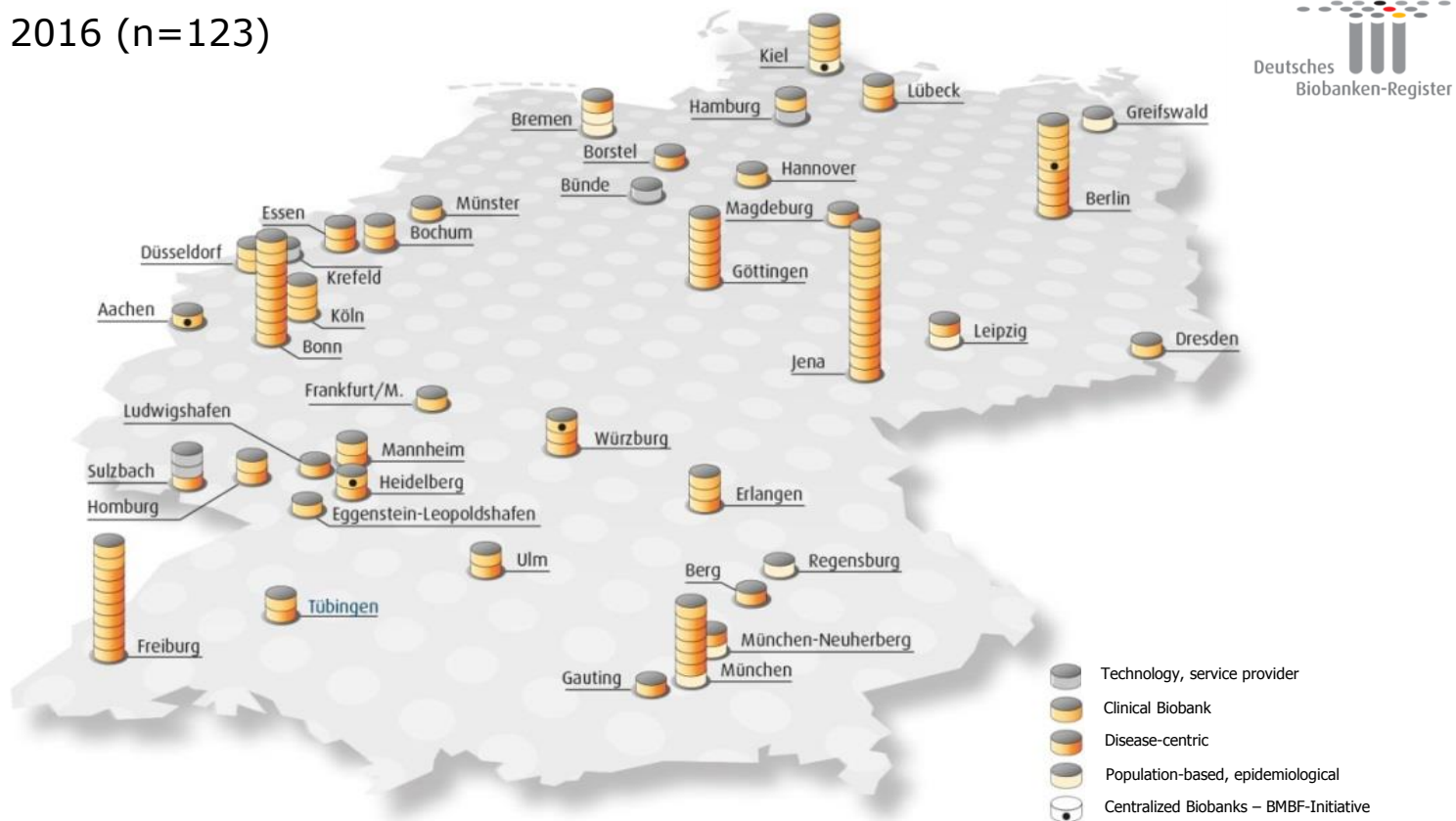


since 2008	associated member of BBMRI
2008-2009	pilot study on the networking of biobanks in the German Competence Networks
2010-2012	establishment of a sample locator (P2B2) and project mediation portal, jointly with Fraunhofer IBMT Potsdam
since 2008	continuous exchange of expertise through site-visits <i>Graz (AT) 2008, Tartu (EE) 2010, Karolinska 2011 (SE), IBBL (LU) 2011, UK Biobank (GB) 2012, deCODE genetics (IS) 2013, THL/Auria (FI) 2015</i>
2012	ESBB membership (European chapter of International Society for Biological and Environmental Repositories, ISBER)
2013/14	ISBER membership, ISBER Associate
2014	partner of the German Biobank Node (BBMRI.de)

- 2003 first survey of German biobanks
- 2005-2006 second survey (in connection with opinion report for TAB)
- 2007-2009 TMF pilot project for a German biobank register
- 2009-2012 BMBF-funded project "German Biobank Register and User Portal" (go-live and kick-off: 20.03.2012)
www.biobanken.de
- 2012-2015 continued funding through BMBF grant "MethInfraNet"
- 2015 introduction of the national biobank landscape into the BBMRI-ERIC-Directory of Biobanks in Europe



April 2016 (n=123)



- since 2011 continued support of cBMBs (the centralized Biobank initiative by BMBF)
- BMBH, Heidelberg
 - ibdw, Würzburg
 - cBMB-RWT-Aachen
 - P2N-Network, Kiel
 - ZeBanC, Berlin
- + m4 Biobank Alliance Munich
- + comparable biobank infrastructures
-
- since 2012 provision of National Biobanking Symposium
- 5th symposium scheduled for December 7-8, 2016
- symposium proceedings identifiable by ISBN
(www.amazon.de)



1. Nationales Biobanken-Symposium
2012

Stand und Perspektive der deutschen Biobanken-Infrastrukturen für die medizinische Forschung

Tagungsband –
12. Dezember 2012 | Berlin

2. Nationales Biobanken-Symposium
2013

Zukunft der Biobanken-Forschung in Deutschland: Vernetzung, Kollaborationen und Strukturaufbau

Tagungsband –
11./12. Dezember 2013 | Berlin

3. Nationales Biobanken-Symposium
2014

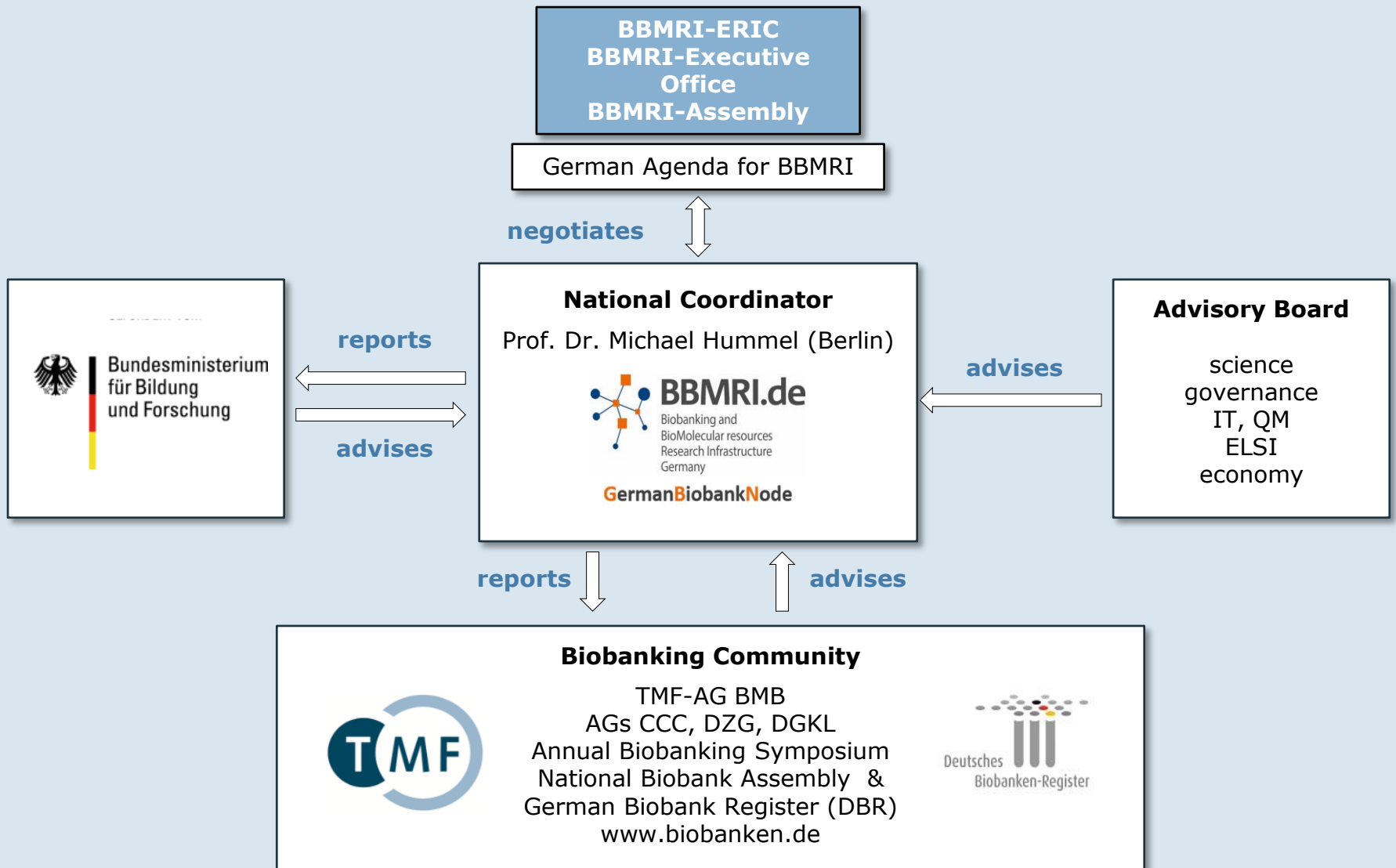
Biobanken-Forschung in Deutschland: Vom Konzept zur Realisierung

Tagungsband –
3. - 4. Dezember 2014 | Berlin

4. Nationales Biobanken-Symposium
2015

Biobanknetzwerke als Schrittmacher der medizinischen Forschung

Tagungsband –
9. - 10. Dezember 2015 | Berlin



Bottom-up approach

- important for acceptance and sustainability

Foster continuous interdisciplinary collaboration

- infrastructural matters
- legal and ethical matters
- methodological matters

Avoid duplication of efforts

- no parallel projects or infrastructure (no “research waste”)
- no diversification of organizations, committees, events etc. unless absolutely necessary

Gain impact

- reliability (services, tools)
- liability (concepts, legal matters)
- political communication



**Thank you
for your attention!**

Enjoy Berlin!

Further information:

- <http://www.tmf-ev.de/>
- info@tmf-ev.de
- www.tmf-ev.de/EnglishSite/WorkingGroups/Biobankingworkinggroup.aspx