Implications of GDPR for US-EU Cooperation in Biomedical Science

Observations from the US National Institutes of Health
NIH By the Numbers

• $39 billion investment

• 80% of the NIH's funding awarded through almost 50,000 competitive grants to 300,000+ researchers

• Supporting more than 2,500 universities, medical schools, and other research institutions in U.S. and abroad

• Approx. 10% of the NIH's budget supports projects conducted by nearly 6,000 scientists in its intramural laboratories

• Represents estimated 39% of global spending on global health R&D (G-Finder survey)

https://www.nih.gov/institutes-nih
Present Scope of US-EU Activity Under NIH Sponsorship

Around 5,000 collaborative projects across EEA with US institutions
US- EU Cooperation in Biomedical Science

Four Transformative Opportunities:

1. Alzheimer’s disease prevention and therapy
2. Cancer immunotherapy
3. Gene-based curative therapy
4. Precision or personalized medicine
Addressing Shared Policy Challenges

• Harnessing the power of big data
  • Data sharing policies, common standards, interoperable resources
Why US-EU Cooperation Will Accelerate Progress from Bench to Bedside

- Genetic vs. clinical characterization of study volunteers
  - Expands need for cross border cooperation
- Use of targeted therapy for uncommon diseases/subtypes of common diseases
  - Similarly requires more widespread recruitment
- Demonstrated value of large, cross national cohort studies as platforms for discovery
  - Blood pressure, genome wide associations, and rare genotypes
- Sharing and leveraging of novel technologies, and other cost sharing collaborations
  - Eliminates redundancies
GDPR’s Early Implementation: Some Competing Attributes

- Data privacy vs. open science
- Harmonization vs. member state autonomy
- Data anonymization vs. scientific utility
Representative Example of Data Transfer Impediments

• Finnish National Institute of Health and Welfare (THL) Genomic Studies of Type 2 Diabetes

• International Blood & Marrow Transplant Research Program

• Alzheimer’s Disease Sequencing Project
Major Challenges and Ambiguities for the US Scientific Community

• Appropriate legal basis for processing personal data, including special categories
• Varying standards of anonymization across EEA
• Requirements for consent for future research uses
• Complying with right to withdraw, while meeting ethical/legal obligations to retain data
• Legal basis for data transfers outside EEA when standard contractual clauses are not feasible
Possible Paths Forward

• Pursue code of conduct that creatively reconciles differences in EU-US data privacy standards, for EU approval

• Secure greater clarity on use of bespoke clauses and applications of Article 49 derogations

• Seek more uniform and workable definition of anonymization

• Develop template data use agreements and consent form clauses, to be adapted by US-EU investigators and consortia

• Develop platforms to share preferred or best practice in implementing GDPR, to reduce current risk averse behaviors across Europe