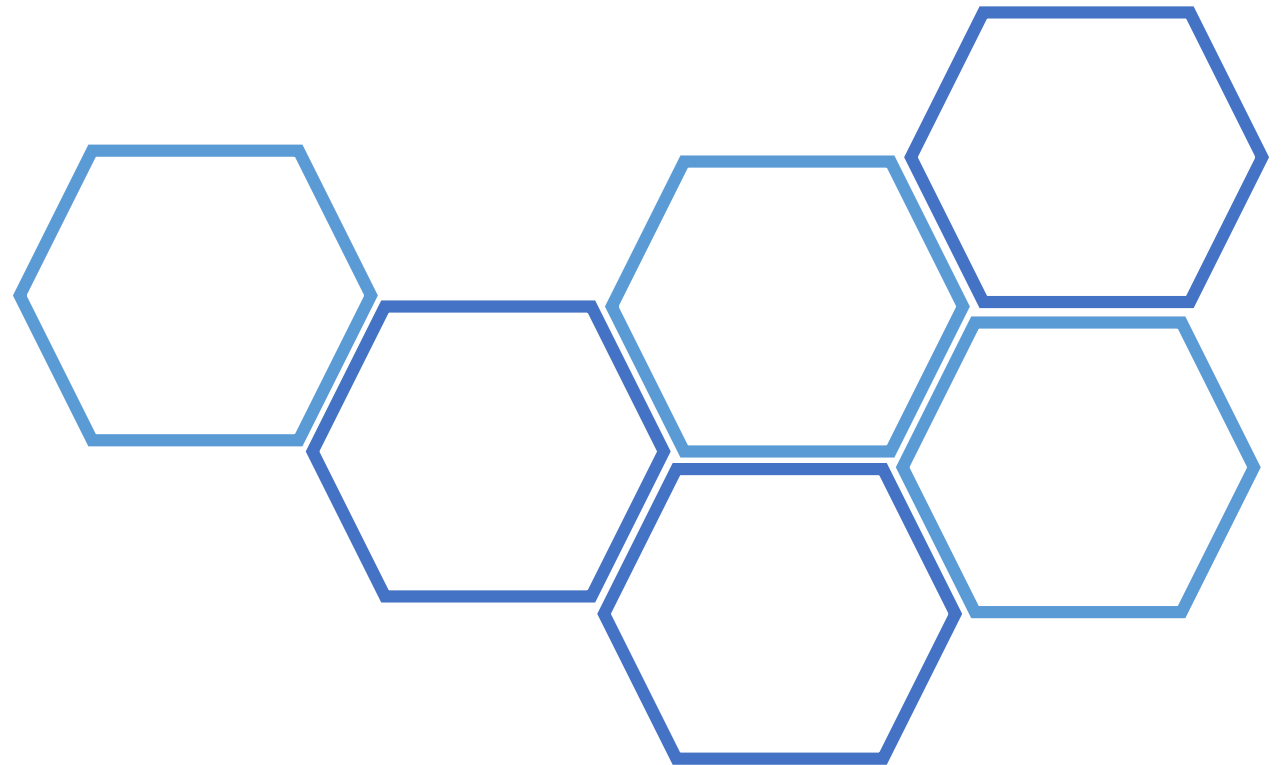


Implications of GDPR for US-EU Cooperation in Biomedical Science

*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

#	EEA Countries	# of Direct Awards	# of Collaborations	Visiting Scientists
1	Austria	0	96	6
2	Belgium	2	134	4
3	Bulgaria	0	4	1
4	Croatia	0	10	3
5	Cyprus	0	4	1
6	Czech Republic	0	28	5
7	Denmark	1	186	3
8	Estonia	0	13	1
9	Finland	1	93	5
10	France	13	499	63
11	Germany	17	899	57
12	Greece	0	22	18
13	Hungary	0	27	7
14	Iceland	0	27	0
15	Ireland	2	70	13
16	Italy	1	284	66
17	Latvia	0	1	0
18	Liechtenstein	0	0	0
19	Lithuania	0	6	0
20	Luxembourg	0	6	0
21	Malta	0	0	1
22	Netherlands	9	383	9
23	Norway	0	94	1
24	Poland	0	40	12
25	Portugal	0	39	10
26	Romania	0	17	3
27	Slovakia	0	4	5
28	Slovenia	0	13	0
29	Spain	1	268	40
30	Sweden	8	292	12
31	United Kingdom	47	1437	53
	TOTALS	102	4996	399

US- EU Cooperation in Biomedical Science

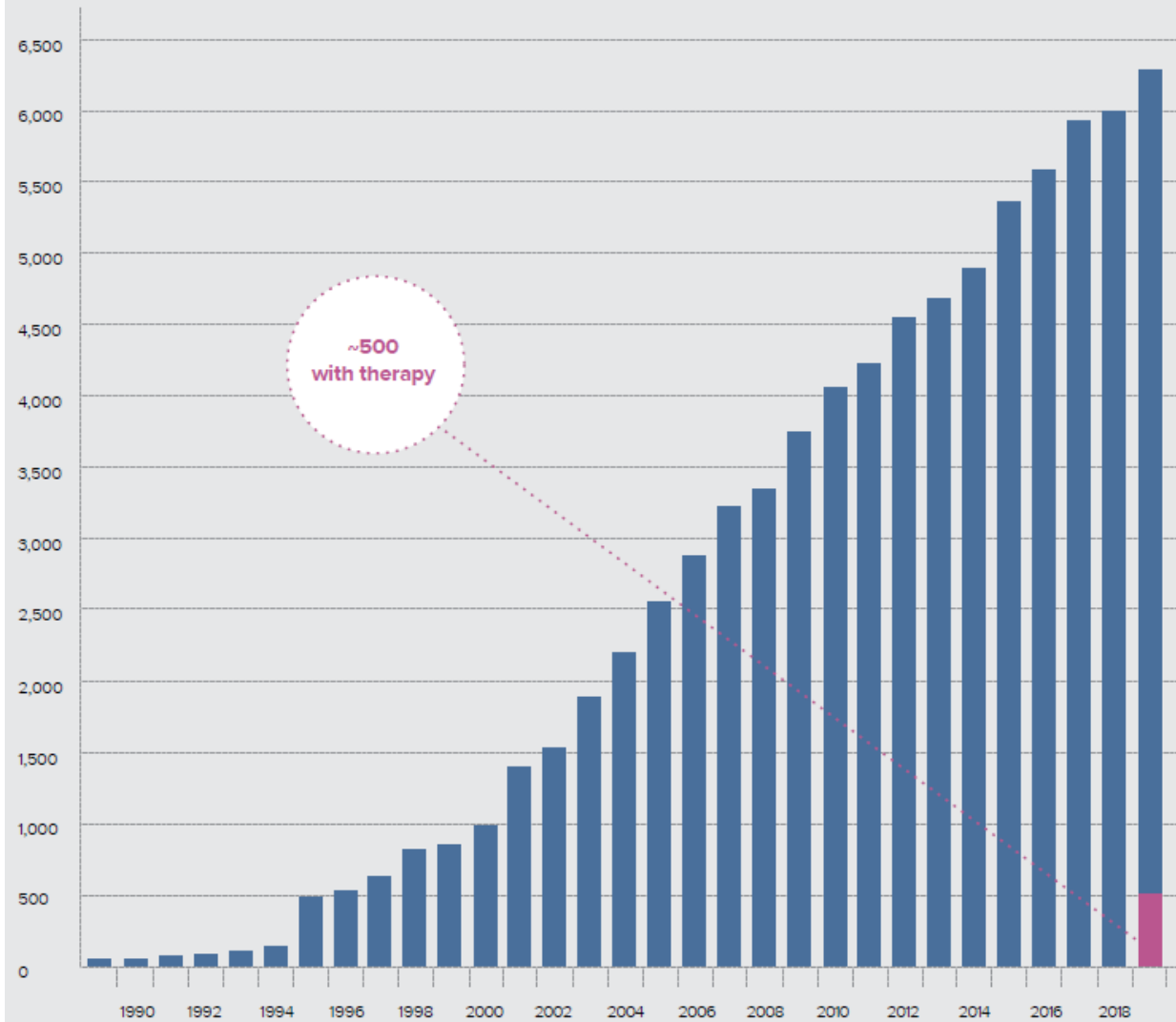
Four Transformative Opportunities:

1. Alzheimer's disease prevention and therapy
2. Cancer immunotherapy
3. Gene-based curative therapy
4. Precision or personalized medicine



FIGURE 4.1

Disorders with known molecular basis

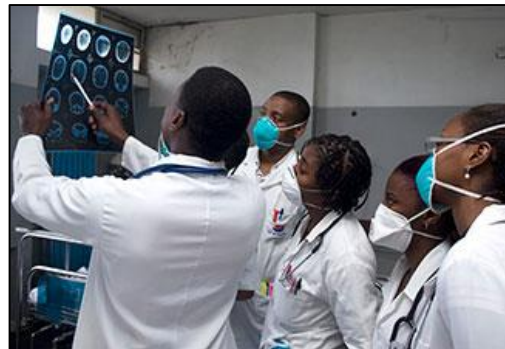


The Global Innovation Index 2019, Chapter 4 NIH

Source: Online Mendelian
Inheritance in Man, available at.
[https://www.omim.org/statistics/
geneMap](https://www.omim.org/statistics/geneMap)

Addressing Shared Policy Challenges

- Harnessing the power of big data
 - Data sharing policies, common standards, interoperable resources

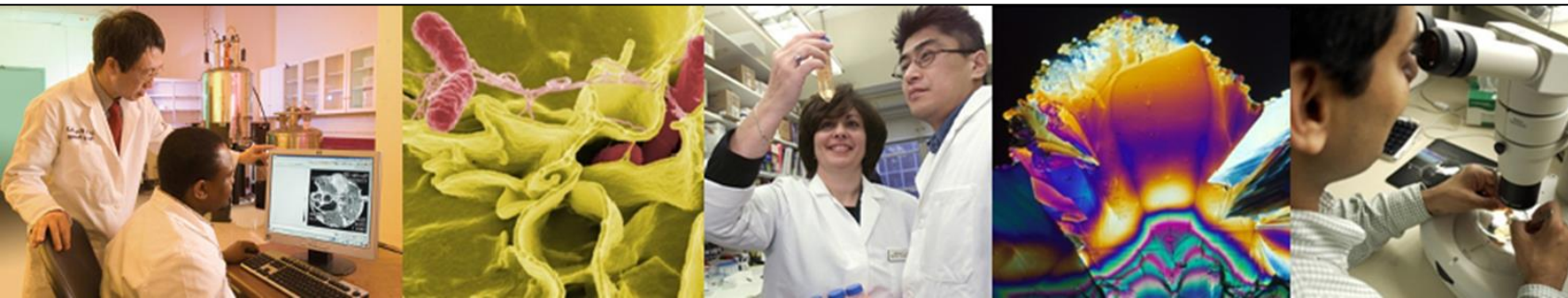


Why US-EU Cooperation Will Accelerate Progress from Bench to Bedside

- 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