

Challenges & Opportunities in Data Sharing

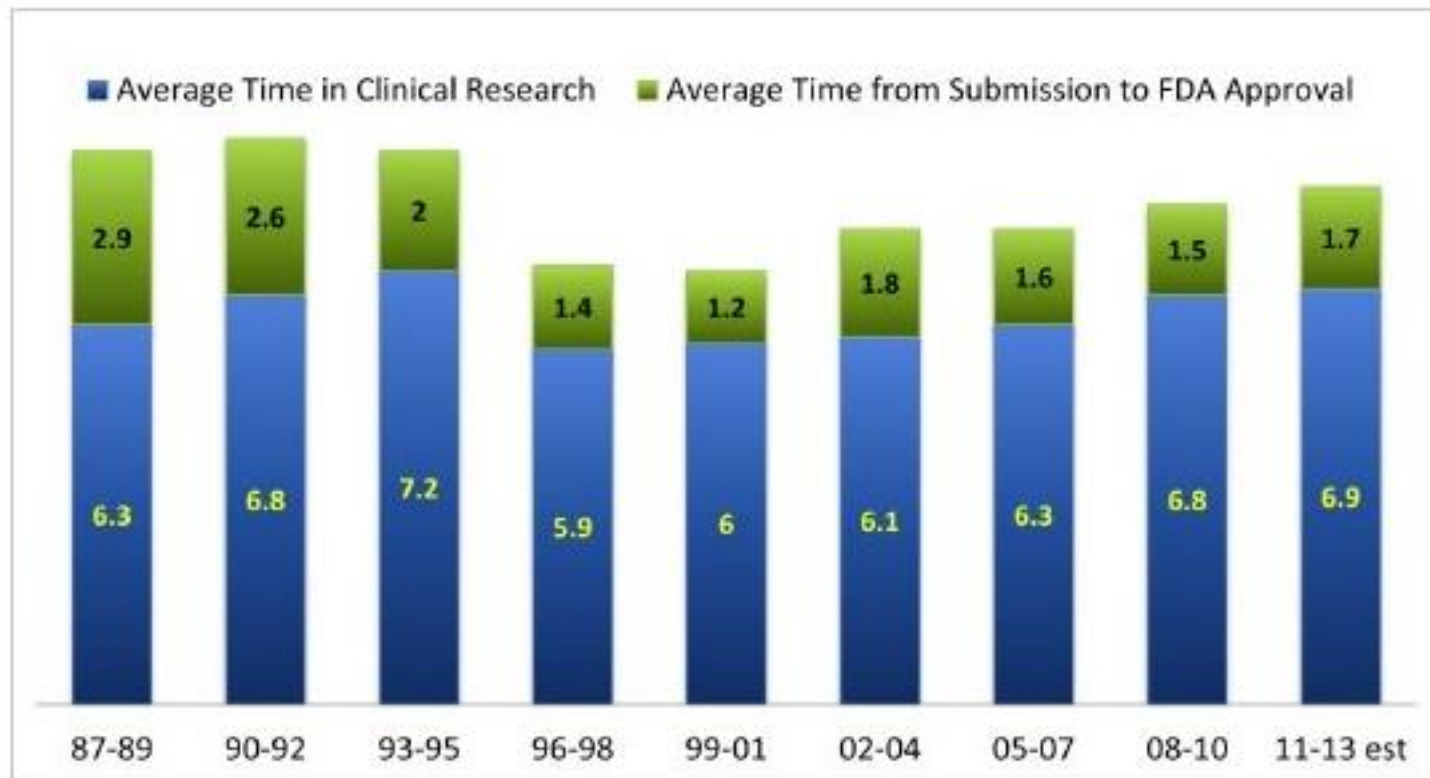
Dr. Samir N. Khleif

Critical Areas for Biomarker Development

- Biospecimens
- Analytical Performance
- Standardization and Harmonization
- Bioinformatics
- Collaboration and Data Sharing
- Stakeholder Education and Communication
- Regulatory challenges
- Science Policy

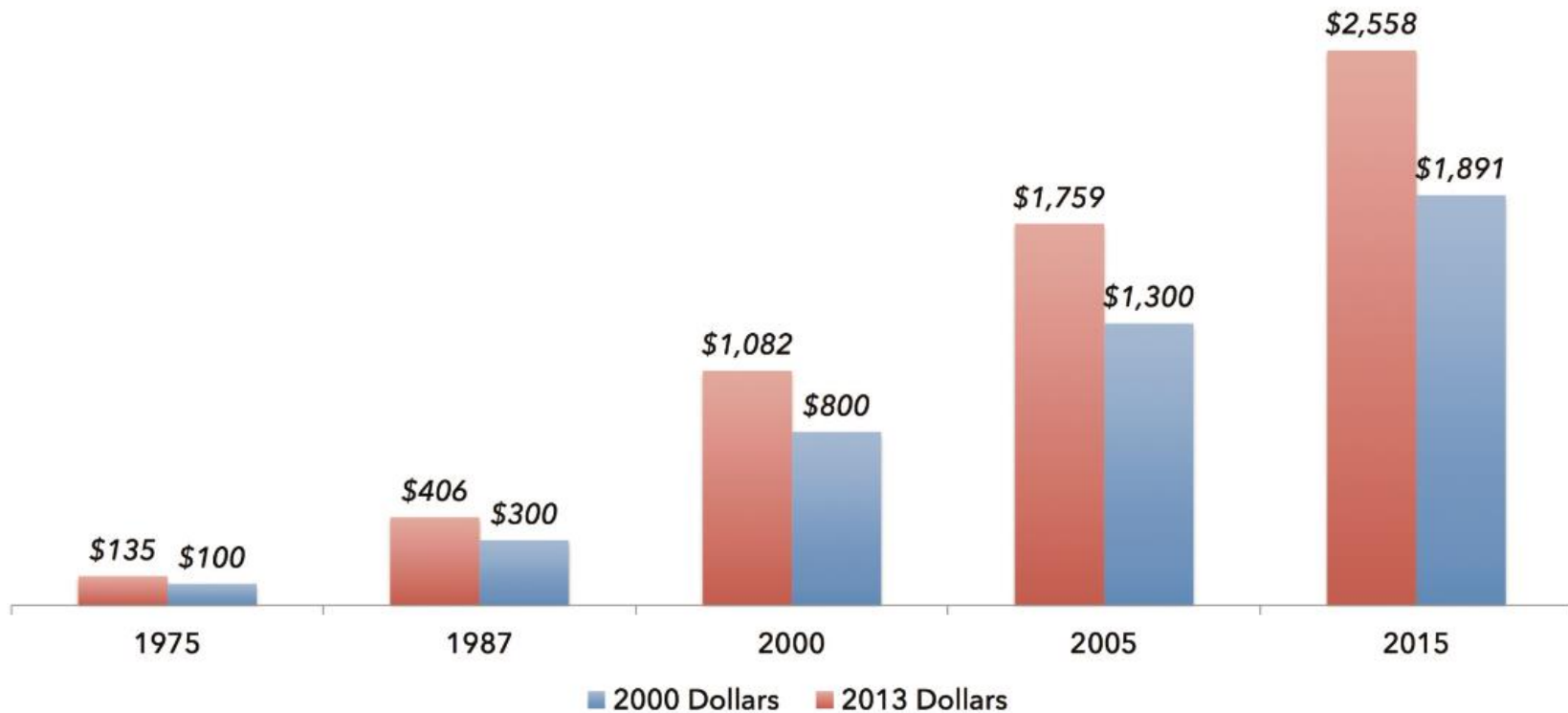
Collaboration and Data Sharing

Time in Years from the Beginning of Clinical Research to FDA Approval

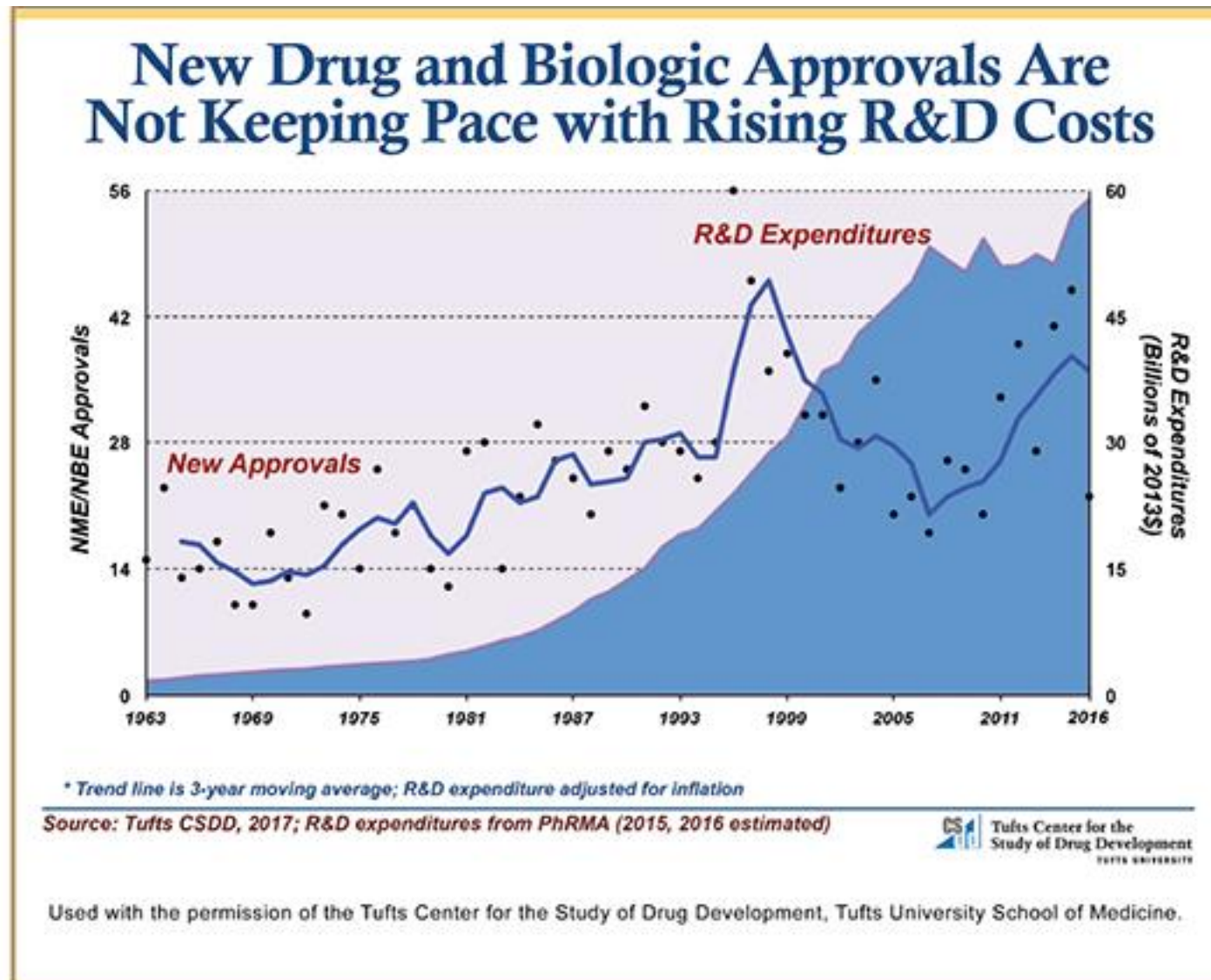


Collaboration and Data Sharing

Figure 7. R&D Expenditures per FDA-Approved Drug (\$ Millions)



Collaboration and Data Sharing



Data Sharing in Academia

Nullius In Verba



Royal Society 1660

Don't Take nobodies' word for it



Royal Society 1660

Data sharing

- Reinforces open scientific inquiry
- Encourages diversity of analysis and opinion
- Promotes new research, testing of new or alternative hypotheses and methods of analysis
- Supports studies on data collection methods and measurement
- Facilitates education of new researchers
- Enables the exploration of topics not envisioned by the initial investigators
- Fosters creation of new datasets by combining data from multiple sources

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The challenges of data sharing

- **Ethical |**
 - Responsible management of personal or sensitive data
 - Unverified / peer-unreviewed data
 - Data ownership and publications
 - Meaningful compatibility of data – Same nomenclature, comparable experimental conditions

The challenges of data sharing

- **Ethical |**
- **Legal |**
 - Uncertainty around privacy regulations and the associated impacts on data sharing – **how tight is the system ??!**
 - Deliberate legal process in the academic space
 - Cross borders exchange- disadvantage many

The challenges of data sharing

- **Ethical |**
- **Legal |**
- **Cultural |**
 - The reluctance of investigators to share research data due to fears of misuse
 - Claiming credit
 - Promotion and Tenure process
 - NEJM – “Research Parasites” vs. “Research Symbiosis”

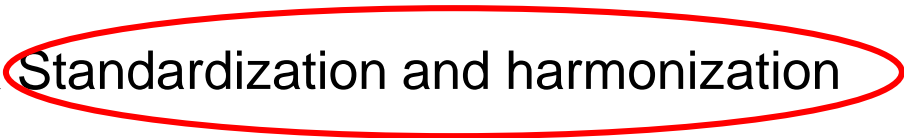
The challenges of data sharing

- **Ethical |**
- **Legal |**
- **Cultural |**
- **Financial |**
 - Resultant IP ownership
 - Costs of implementing data sharing solutions are high and might not have an immediate return

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- **Technical |**
 - Data storage, management, and analysis must be robust and reliable
 - Meaningful compatibility of data Standardization and harmonization of data

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Standardization and Harmonization

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- No comprehensive effort to develop necessary standards

Standardization and Harmonization

- **Terminology**—Harmonize biomarker validation and qualification terminology
- **Data Standards**—Develop a set of common data standards in which the community has influence and input
- **Biospecimen Annotation**—Define a universal data element set to accompany all high-quality biospecimens

Biospecimens Sharing

Biospecimens Sharing

- Lack of standardize QA
- No uniformly applied Standards (TCAG)
- No evidence based best practices
- Complete lack of support of biospecimen research

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Data Sharing

The
Economist

Regulating the internet giants

The world's most valuable resource is no longer oil, but data

What's Next

- Clarification of legal and ethical uncertainties regarding privacy concerns and regulations
- Data standardization
- Restructure the academic incentives – universities and Med Schools

What's Next

- Advanced planning for sharing participant-level data at the outset of a study *NEJM*
 - Symbiotic
 - Identify potential collaborators whose data may be useful
 - Pre determined new hypothesis
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 - Symbiotic
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- Better research policies to incentivize research data sharing, particularly in academia
 - Formal recognition
 - Financial Reimbursement
 - Journals adopting mandatory data sharing policies

reaching beyond Nullius In Verba

21st Century