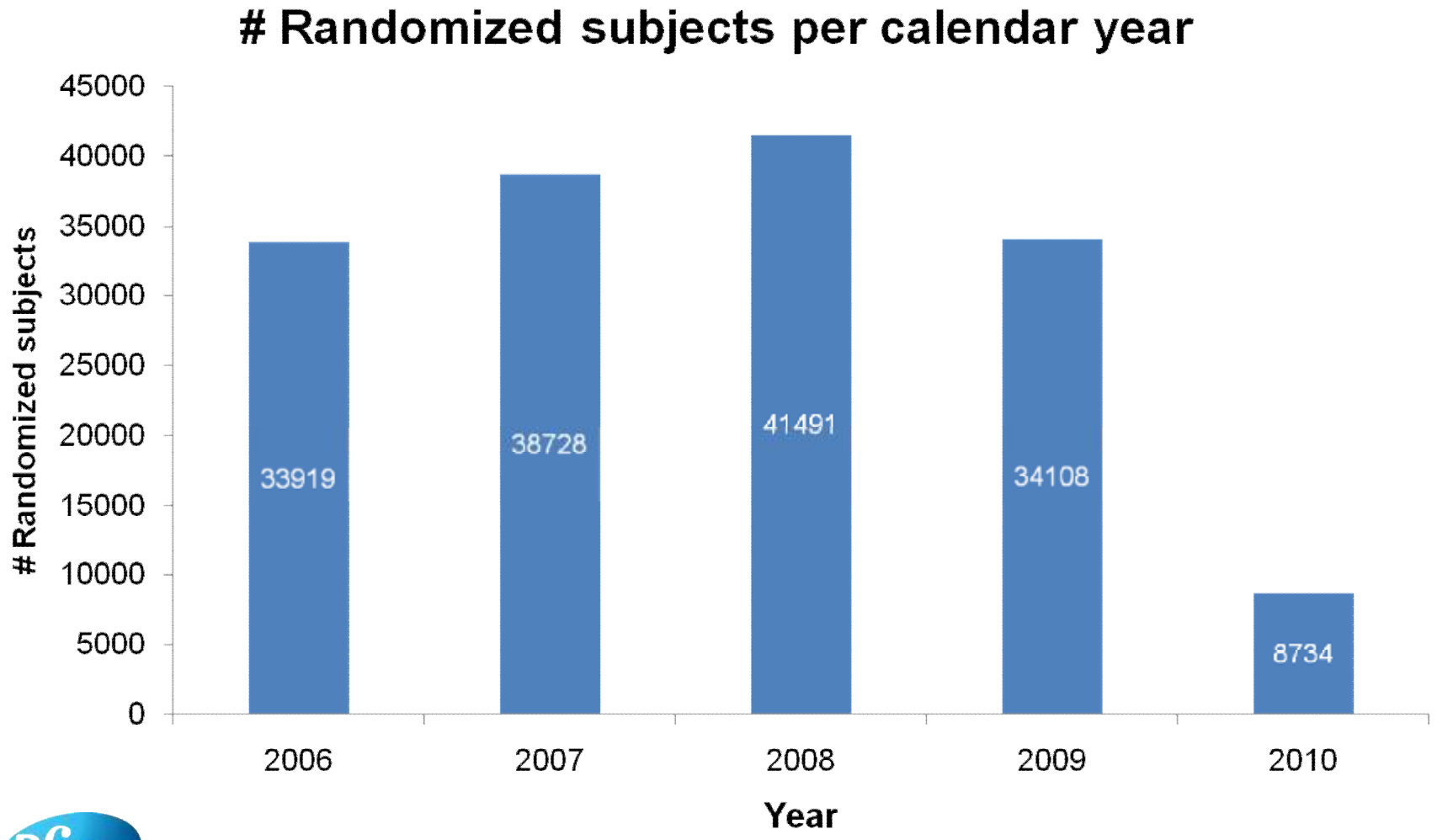
Opportunities and challenges of data access in the pharmaceutical industry

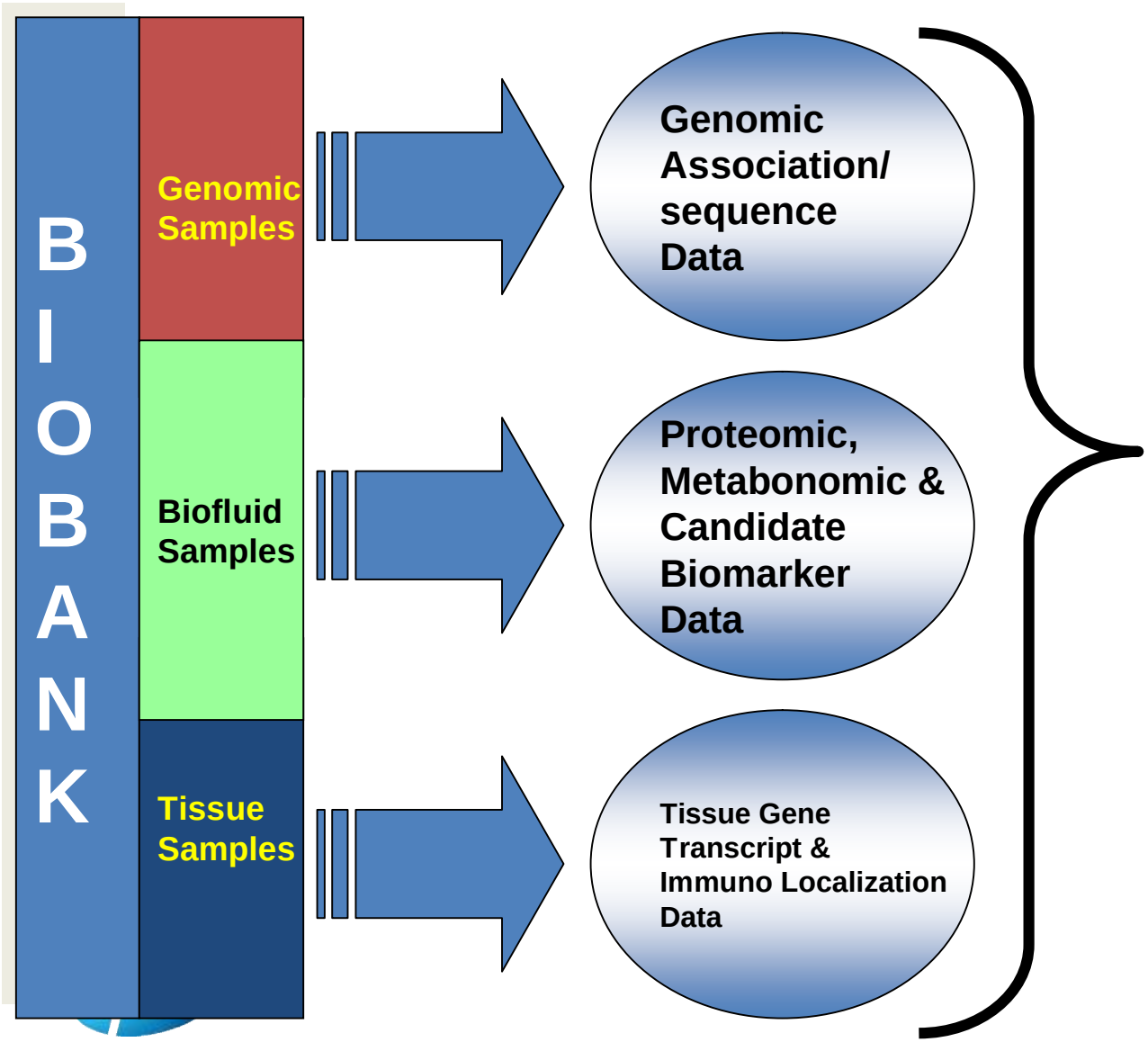
Sally John

22nd July 2010, IOM workshop
Washington DC

Clinical trials provide a rich source of research data



Use of Samples to Facilitate Drug Discovery and patient stratification



- **Results:**
- **Expanding our Understanding of Disease Physiology and Pathophysiology**

- **Impacts:**
- **New Targets**
- **Impact on Confidence for Current Targets**
- **Biomarkers: Efficacy & Safety**
- **Patient Population Selection Tools**

Biobanked samples for research use

Therapeutic Area	# Human Samples	# Drug Programs	Sample Type(s) Represented
Cardiovascular disorders	50,000	11	DNA
Congenital & familial disorders	>2000	1	DNA
Eye disorders	1500	3	DNA, serum
Endocrine, metabolism & nutritional disorders	25,000	12	DNA, serum
Musculoskeletal & connective tissue disorders	44,000	29	DNA, plasma, serum, urine
Nervous system & psychiatric disorders	30,000	39	DNA, plasma, serum, urine
Renal, urinary & reproductive disorders	5,000	13	DNA, urine

Opportunities of increasing access to data – What should be motivating industry?

- **Demonstrates a commitment to strong science and human research**
- **We need to develop robust predictive models of disease**
  - Requires large multivariate data generated in humans
- **Enable meta or mega-analysis of multiple data sets**
  - More robust data on which to base decisions
  - More power to detect modest effect sizes
  - Tighter estimates of effect sizes
  - Rapid replication and validation of exploratory findings
- **Attracts funding for clinical research to address questions that are common across industry**

Recent examples of good quality studies

Public private partnership

nature genetics

*HLA-B*5701* genotype is a major determinant of drug-induced liver injury due to flucloxacillin

Ann K Daly[1], Peter T Donaldson[1], Pallav Bhatnagar[1], Yufeng Shen[2], Itsik Pe'er[2], Aris Floratos[2], Mark J Daly[3], David B Goldstein[4], Sally John[5], Matthew R Nelson[6], Julia Graham[1], B Kevin Park[7], John F Dillon[8], William Bernal[9], Heather J Cordell[1], Munir Pirmohamed[7], Guruprasad P Aithal[10,11] & Christopher P Day[1,11], for the DILIGEN study[12] and International SAE Consortium[12]

Twelve type 2 diabetes susceptibility loci identified through large-scale association analysis

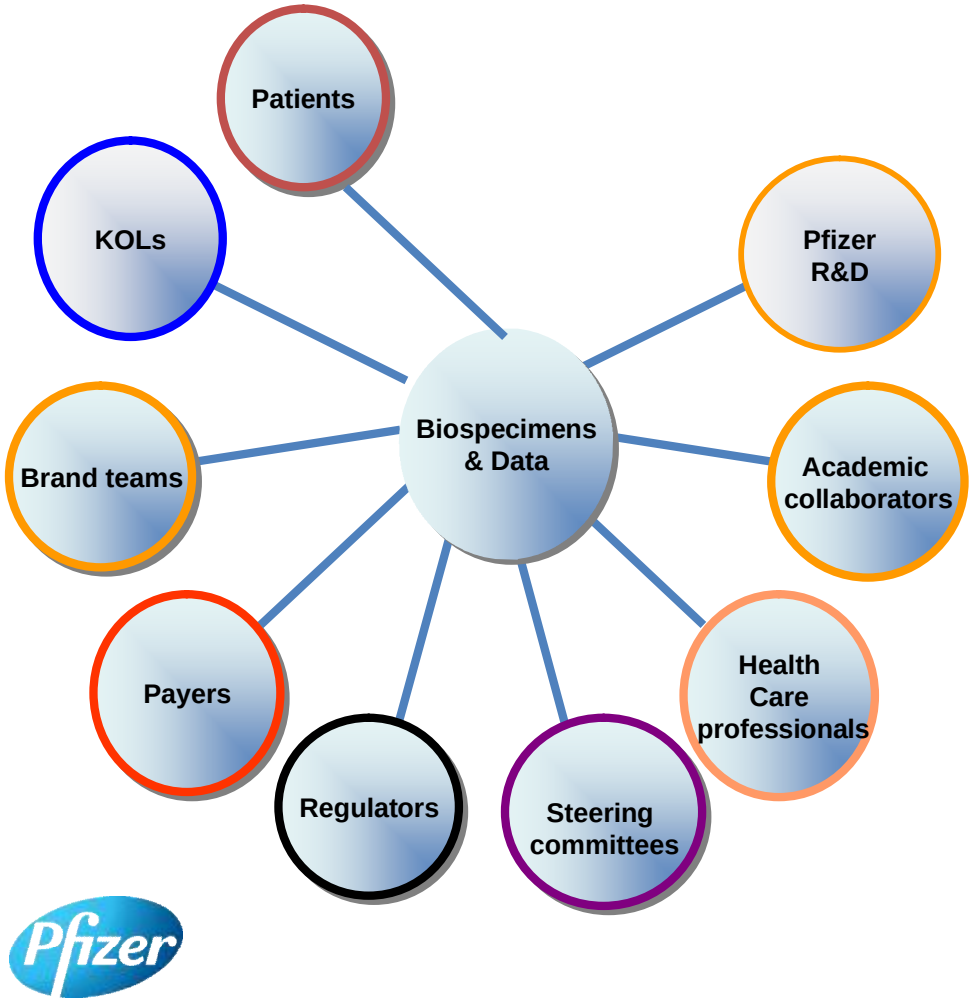
By combining genome-wide association data from 8,130 individuals with type 2 diabetes (T2D) and 38,987 controls of European descent and following up previously unidentified meta-analysis signals in a further 34,412 cases and 59,925 controls,

> 45,000 subjects

No industry affiliations

Pfizer

Who might benefit from collaborative use of Pfizer bio-specimens and data?



Potential value or benefit is usually anticipated based on as yet unknown results

A key challenge is balanced the needs and expectations of different groups

Experiences and issues experienced

- **No standard process**
- **Requests come via….**
  - Investigator initiated research
  - Clinical Trial Steering Committee
  - Pfizer/academic collaboration
  - Precompetitive consortium (e.g.iSAEC, FNIH, IMI in Europe)

Issues
- **Pfizer informed consent allows access to data only within a collaboration with Pfizer**
- **Business value perceived as low internally**
- **Some academic consortium are "virtual entities "**
- **May need permission / endorsement from internal and external stakeholders**
- **Concern from clinical teams**
- **Biobank resource required to deliver large biospecimen orders**
- **Expectation from academic partner s that industry will foot the bill.**
- **A view that large consortium never deliver anything.**

Best practices and structure

- **Simplify the process to access biospecimens and data and seek endorsement from stakeholders early**
  - Develop a “take it or leave it” approach for terms and conditions of access
- **The more standardized across industry the better**
- **All data generated must be returned to central database with the expectation of additional meta-analysis**
- **Industry partners need to ensure skilled experts are fully engaged with pre-competitive effort**
  - Precompetitive research is not a spectator sport!

Pfizer

Incentives

- **Precompetitive efforts focused on problems relevant to drug discovery / development**
  - Innovative medicine initiative established to address specific bottlenecks in drug discovery
- **Commitment from all partners to publish all results and data**
- **Methods for rewarding both academics and industry for making biospecimens and data available**
- **Acknowledge the cost of Pharma of collecting these data and samples**
  - Some funding to support operational aspects of precompetitive research
- **Concomitant investment in bioinformatics tools and methods to enable maximum use of results by all parties**

Discussion – session questions

- 1. What are the unique issues [technical, cultural, ethical] in sharing biospecimens (and data) that need to be considered in a sharing framework?
- 2. What have you learned from your initiative that could be used to define 'best practices' for specimen and data sharing?
- 3. What should motive industry stakeholders to share specimens and data with each other and with the broader investigator community? – opportunities slide
- 4. What incentives should or need to be in place to encourage sharing of biospecimens and data?
-
- 5. What key structures and/or rules do you think are required for a framework of sharing biospecimens and data?