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**LEGAL AND REGULATORY ISSUES IN  
REGISTRY GROWTH AND  
SUSTAINABILITY MODELS**

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# Road Map

- IP 101
- Background on Ownership of Registry Data
- Growth and Sustainability Models
- Legal/Contractual Issues
- Regulatory Issues

# IP 101

- IP rights fall into several categories
  - Copyright
  - Trademark/Service Mark
  - Patent
  - Trade Secrets

# IP 101

- IP rights fall into several categories
  - Copyright
    - Protected by federal copyright law and common law
    - Original works of authorship fixed in any tangible medium of expression
    - Includes compilations and arrangements of data that are “selected, coordinated, or arranged in such a way that the resulting work as a whole constitutes an original work of authorship”
    - So, registry databases, data fields, data elements, and data dictionaries may all be protected by copyright
    - Registration of copyright with the federal Copyright Office can provide additional protection, but not practical for most registry IP
    - © [name of registry] [year]. All rights reserved.

# IP 101

- IP rights fall into several categories
  - Patent
    - Federal patent law protects first use of novel inventions, including processes or methods
    - No common law equivalent
    - Patent law precludes others from using or selling the patented process or method without permission of the patent holder for 20 years
    - Some registry technology or algorithms may be patentable, but patent application and review process is very time consuming and expensive

# IP 101

- IP rights fall into several categories
  - Trademark/Service Mark
    - Federal trademark law and common law protect trademarks and service marks
    - Trademarks protect brand names, usually for products
    - Service marks are a type of trademark that protect names, logos, and tag lines or slogans
    - Registry name, logo, and tag lines can and should be registered with the US Patent and Trademark Office
    - ® vs. TM vs. SM

# IP 101

- IP rights fall into several categories
  - Trade Secrets
    - No formal federal statutory protection
    - Uniform Trade Secrets Act has been adopted by most states
    - "**Trade secret**" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.
    - Registry technology, algorithms, etc. may be protected trade secrets



# Ownership of Registry Data

- Database participation agreement defines the applicable terms of participation
- Database participation and vendor agreements should clarify ownership of data
  - Distinguish between raw data and the database
  - Typically sites will retain ownership of raw data they submit
  - Database owner will own:
    - The database (including the aggregate data and subsets of data, data fields/elements, etc.)
    - Any reports/analysis based on the data
    - Information derived from the data
    - All trademarks, trade secrets, and intellectual property arising from or reflected in the database
  - Patients have interest in data but generally not ownership
  - Check state law--<http://www.healthinfolaw.org/comparative-analysis/who-owns-medical-records-50-state-comparison>

# Growth & Sustainability Models

- Data Sharing with:
  - Industry
  - Academia
  - Government
  - Data analytic centers
  - Other Registries
- Registry-to-Registry Ventures
- Government/Foundation Grants
- User Fees/MIPS-QCDR Reporting
- Research/Clinical Trials

# Legal/Contractual Issues

- Data Sharing
  - Consistency with tax-exempt purpose
    - Research or public health purpose
    - Not selling data
  - Allocate rights in data, derivative products, other IP
    - Registry vs. industry sponsor
    - Ownership vs. license
    - Subject to rights of participants, patients, other data sources
  - Access/use of data after termination
  - Research and publications process
  - Liability protections/disclaimers

# Legal/Contractual Issues

- Registry to Registry Ventures
  - Data Sharing/Linking
  - Joint ventures for specific projects
  - Jointly-sponsored registries
  - Consolidations
    - Merger
    - Asset transfer
    - Data transfer
  - Allocate IP rights in shared or linked data
  - Importance of escape clauses

# Legal/Contractual Issues

- Government/Foundation Grants
  - Federal Grants (most likely HHS)
    - Need to comply with extensive HHS rules for federal grant recipients
    - Government retains broad rights in data and other IP collected/created using federal funds, but not existing data or other IP
  - Foundations or other funders (e.g., PCORI)
    - Pay attention to funding conditions
    - Allocation of IP rights

# Legal/Contractual Issues

- User Fees/MIPS-QCQR Reporting
  - Fees established through participation/site agreements or subscription agreements
  - Subscription agreements for use of dashboards may be more palatable for some hospitals and physician groups
  - MIPS/QCQR Reporting requires separate consent and waivers from individual physicians and groups, as well as permission from sites to use their data for reporting on behalf of affiliated physicians

# Legal/Contractual Issues

- Research/Clinical Trials
  - Raises host of legal and regulatory issues that need to be spelled out in agreements with sponsors and sites
  - Many of the same IP issues as with data sharing agreements
  - Currently, research-based registries are more likely to be subsidizing sites than charging fees; but are seeking sponsors

# Regulatory Issues

- HIPAA
  - Full PHI—can only be shared under limited circumstances
    - e.g., with patient authorization, business associates, or IRB waiver
  - Limited Data Sets—can be transferred for research or public health purposes with HIPAA-compliant DUA
  - Can't sell PHI
    - May only receive payment for reasonable costs of preparing and transmitting data
    - Can receive additional payment for other analytic services



# Regulatory Issues

- Common Rule
  - May apply to federally-funded or FDA-related research or to projects with academic medical centers that have signed federal-wide assurances
  - May require IRB review and approval or waiver
- PSOs
  - Cannot transfer PSO data (PSWP) to non-PSO and vice versa
  - Unless data is de-identified

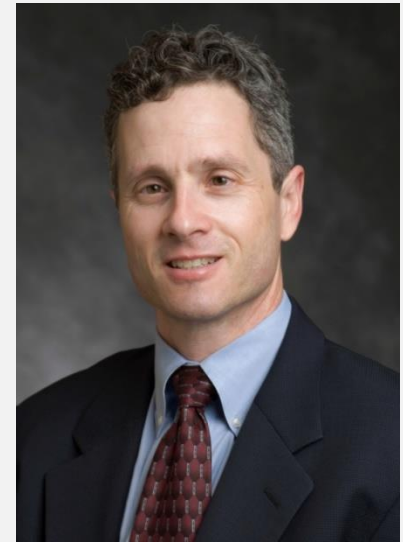
# Regulatory Issues

- FDA Regulations
  - Other FDA regulations relating to consent, MDR reporting, GMPs, etc. would apply to clinical trials for premarket approval or post-market surveillance studies

**QUESTIONS?**

# Robert M. Portman

Robert M. Portman is a principal in the law firm of Powers Pyles Sutter and Verville PC in Washington, DC. Mr. Portman concentrates his practice in health and association law, focusing on legislation and regulation in the health care field, patient privacy, governance, tax exemption, transactions, certification law, administrative law, antitrust, and election and lobbying law. He represents a wide range of non-profit health care organizations including a large number of national professional societies, trade associations, other health care associations, voluntary health organizations and certification bodies, as well as numerous clinical data registries and the Physician Clinical Data Registry Coalition. Mr. Portman graduated *magna cum laude* from Harvard Law School and holds a masters in public policy from the Harvard Kennedy School of Government. He graduated *summa cum laude* from Northwestern University with a BA in Economics.



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