NORTON ROSE FULBRIGHT

Strategic Data Flows: How Data Transactions by Design Can Save your Science (and Sanity)

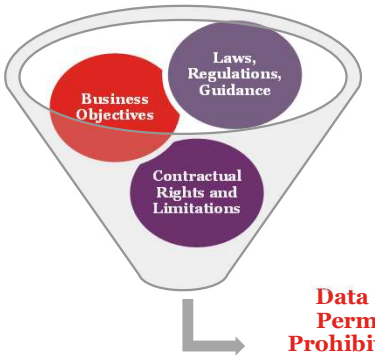
Roger Kuan – Partner (San Francisco)
Jason Novak – Partner (San Francisco)
David Wallace – AGC, Data Science (Johnson & Johnson)

Data Use and Compliance (Key Considerations)

Data Use and Compliance Strategy - A Multi-factorial Approach

How can I:

- Obtain (or restrict) access to data for the intended purpose (development or deployment of solutions, partnerships, research initiatives, etc.)?
- Maximize my ability to use the (or restrict the use of) data for future, secondary purposes?
- Maintain compliance in receiving, using, and/or disclosing the data?



Goals for data

Reliable, accurate and “clean”

Big Data v, Smart Data

Data Use and Compliance Strategy – Plan and Execute

- Compliance
  - Type of Data: Genetic? Medical Records?
  - Standard PHI? De-identified? Anonymized?
  - US (State/Fed)/International data privacy and use laws?
  - BA agreements (as needed)

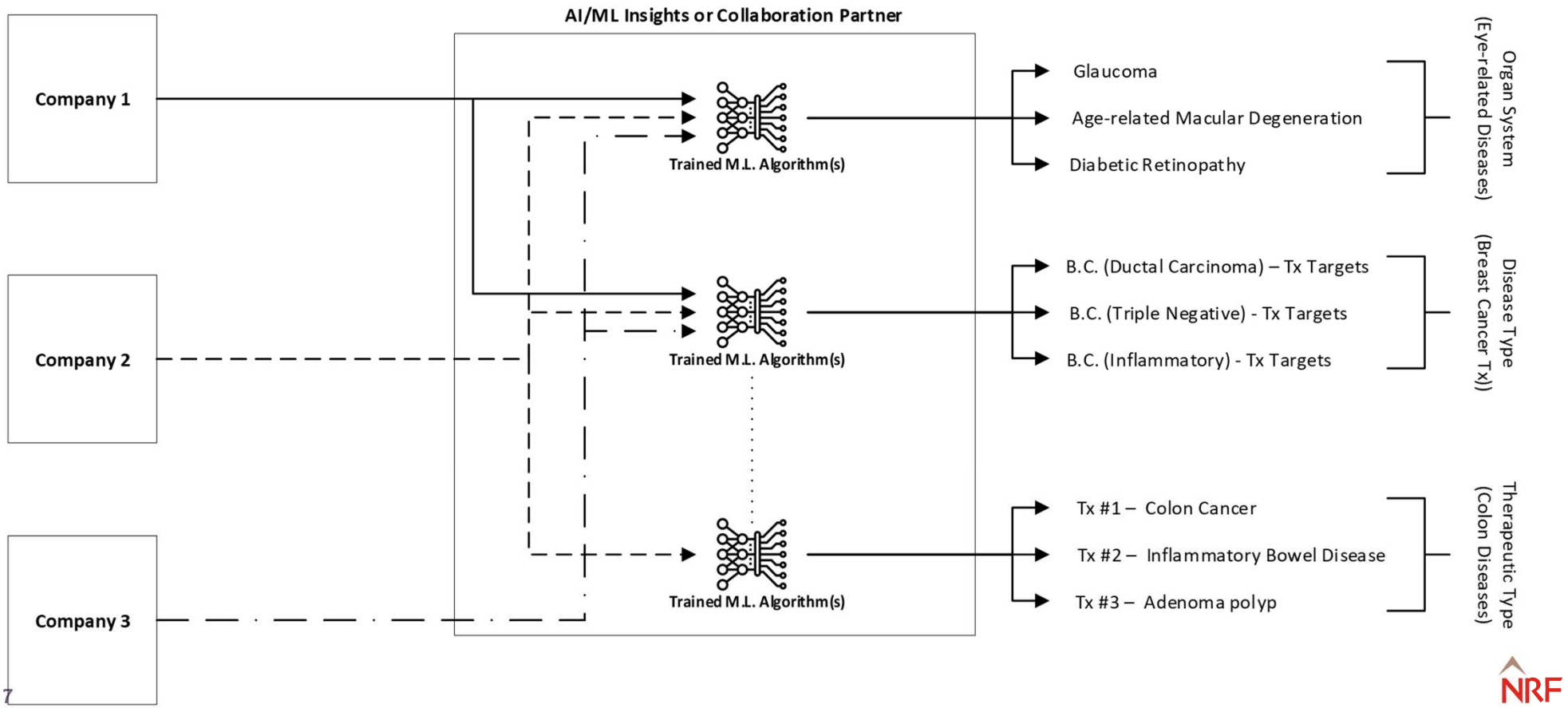
- Access (Now and in the Future)
  - Data Map – map out each use/disclosure of datasets. How will data be utilized (data user) or the kinds of uses permitted for the data (data owner)?
  - Identify scope of consent needed (present and secondary) – Anticipate who secondary users may be
  - What do you want to own? (e.g., insights?, trained models?, IP? etc.)
  - Execute plan – consents, data use restrictions, privacy plan, IP ownership, remedies (including indemnification) from third party licensors/sellers

- Development – downstream of Compliance and Access to prevent tainted development *(no "ready, fire, aim")*

NRF

Structured Approach to Protecting Data Rights in Health Data Transactions

“Generic” Data Use Scenario: Data Map



“Generic” Data Use Scenario (continued)

- Facts: Multiple parties contributing datasets to a data insights collaborator with cutting-edge proprietary AI/ML algorithms that can generate an array of insights and predictions

- How to divide ownership of insights and predictions from AL/ML algorithms trained with data from multiple parties?
  - “Field of Use”
    - Biological application (e.g., organ system, disease target, etc.)
    - Types of insights (e.g., target discovery, etc.)
    - Industry (e.g., pharma, etc.)
    - “Supervised” vs. “Unsupervised” learning
  - RUO vs. Commercial
  - Intellectual property ownership provisions
    - Patents
    - Predictions and insights derived from the particular dataset(s) contributed
    - Specific trained AI/ML model(s)

NRF

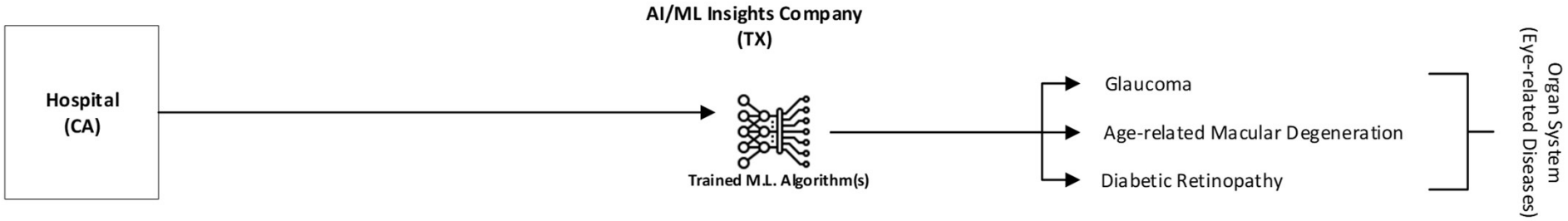
“Generic” Data Use Scenario (continued)

- How to restrict use of data that has been contributed?
  - “Field of Use”
    - Biological application (e.g., organ system, disease state, etc.)
    - Types of insights (e.g., target discovery, etc.)
    - Industry (e.g., pharma, etc.)
    - “Supervised” vs. “Unsupervised” learning
  - RUO vs. Commercial Use
  - Technological Controls
    - Required versioning of trained AI/ML models
    - “Bulk training” vs. “Continuous training”
  - Data destruction clauses
    - Raw Data
    - Trained AI/ML model instance
    - Verification of destruction

NRF

Data Rights and Compliance Considerations (Hypothetical Scenarios)

Data Use Scenario #1 – Data Map (Multi-State)



Data Use Scenario #1 (continued)

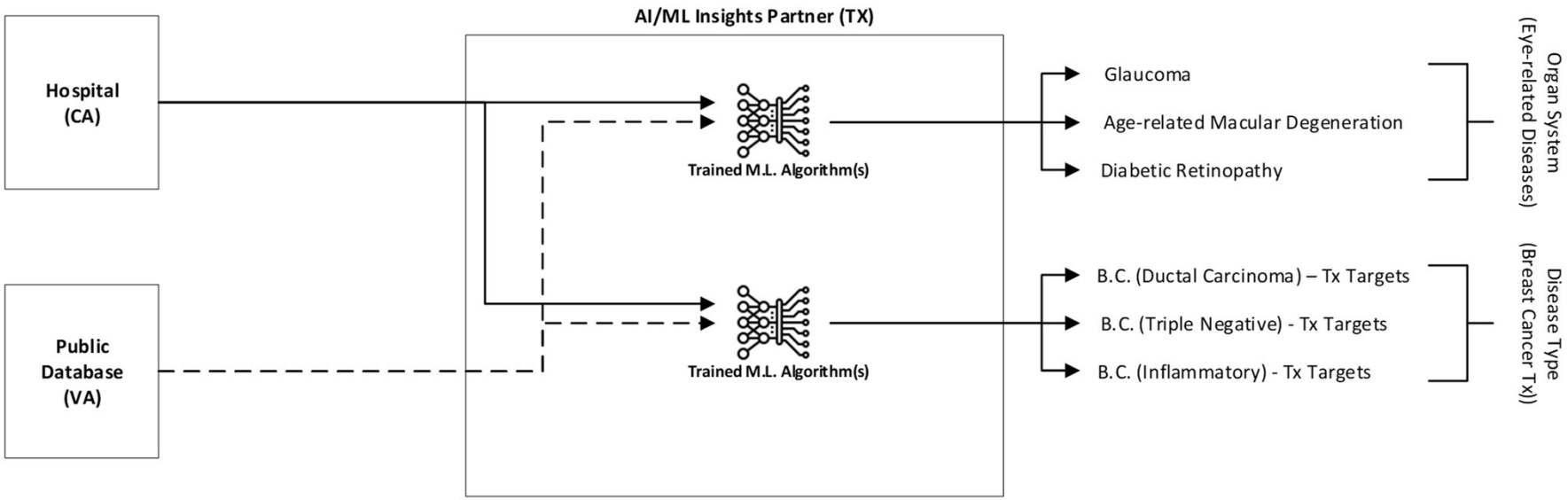
- Facts: California hospital group contributing genomic datasets to a data insights collaborator in Texas with cutting-edge proprietary AI/ML algorithms that can generate an array of insights and predictions

- What are the data regulatory considerations that must be addressed?
  - HIPAA: Applies to PHI obtained from **US Residents** by a **US Covered Entity or Business Associates**
  - California Consumer Privacy Act (CCPA): Applies to PHI obtained from **CA Residents**
  - California Genetic Information Privacy Act (GIPA): Applies to genetic data obtained by direct-to-consumer genetic testing companies from **CA Residents**

- Other considerations?
  - Field of Use
  - RUO vs. Commercial Rights?
  - Ownership of insights
  - Primary and Secondary data rights

NRF

Data Use Scenario #2 – Data Map (Multi-State, Pub Database)



Data Use Scenario #2 (continued)

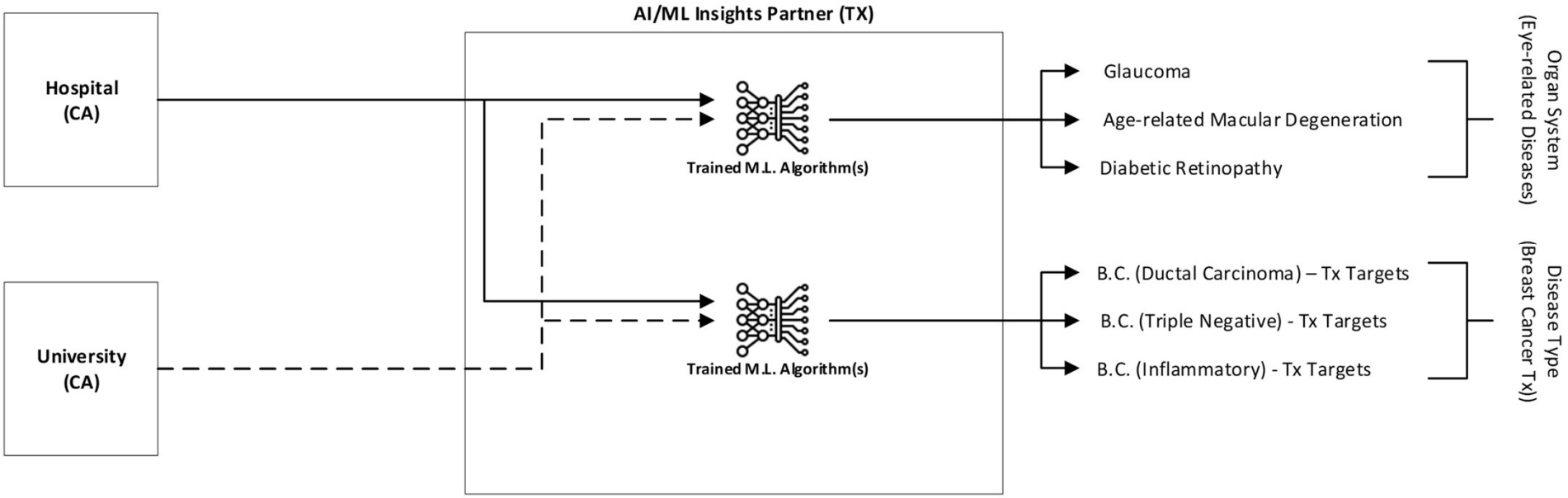
- Facts: Texas-based data insights company with cutting-edge proprietary AI/ML algorithms that can generate an array of insights and predictions, receiving data sets from a California hospital group and Virginia-based Public genomic database.

- What are the data regulatory considerations that must be addressed?
  - HIPAA: Applies to PHI obtained from **US Residents** by a **US Covered Entity or Business Associates**
  - California Consumer Privacy Act (CCPA): Applies to PHI obtained from **CA Residents**
  - Virginia Consumer Data Protection Act (CDPA): Applies to PHI obtained from **VA Residents**
  - California Genetic Information Privacy Act (GIPA): Applies to genetic data obtained by direct-to-consumer genetic testing companies from **CA Residents**

- Other considerations?
  - Field of Use
  - Ownership of insights
  - Primary and Secondary Rights
  - RUO vs. Commercial Rights?

NRF

Data Use Scenario #3 – Data Map (Multi-State, University)



Data Use Scenario #3 (continued)

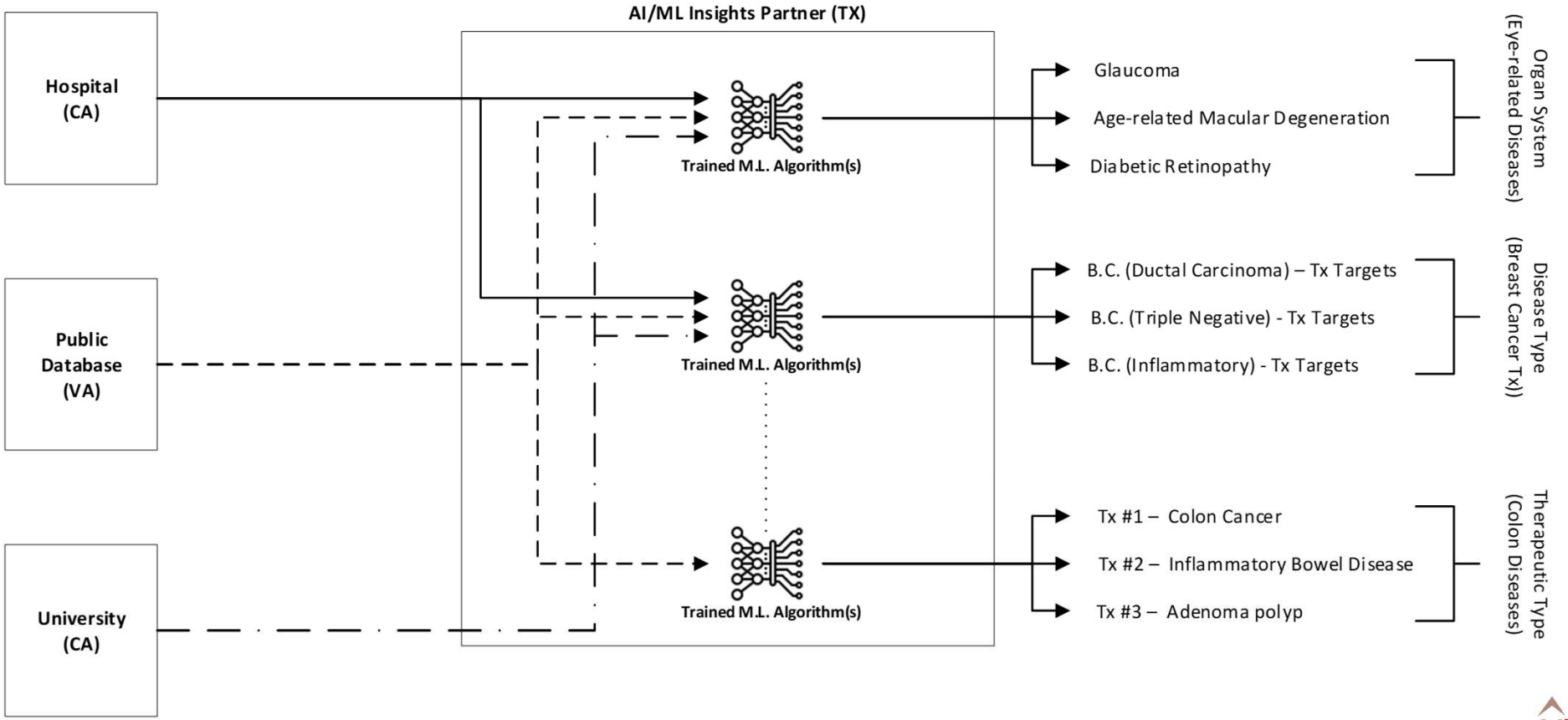
- Facts: Texas-based data insights company with cutting-edge proprietary AI/ML algorithms that can generate an array of insights and predictions, receiving data sets from a California hospital group and a California University.

- What are the data regulatory considerations that must be addressed?
  - HIPAA: Applies to PHI obtained from **US Residents** by a **US Covered Entity or Business Associates**
  - California Consumer Privacy Act (CCPA): Applies to PHI obtained from **CA Residents**
  - California Genetic Information Privacy Act (GIPA): Applies to genetic data obtained by direct-to-consumer genetic testing companies from **CA Residents**

- Other considerations?
  - Field of Use
  - Ownership of insights
  - Primary and Secondary Rights
  - University Audit?

NRF

Data Use Scenario #4 – Data Map (Multi-State, Multi-Entity)



Data Compliance Scenario #4 (continued)

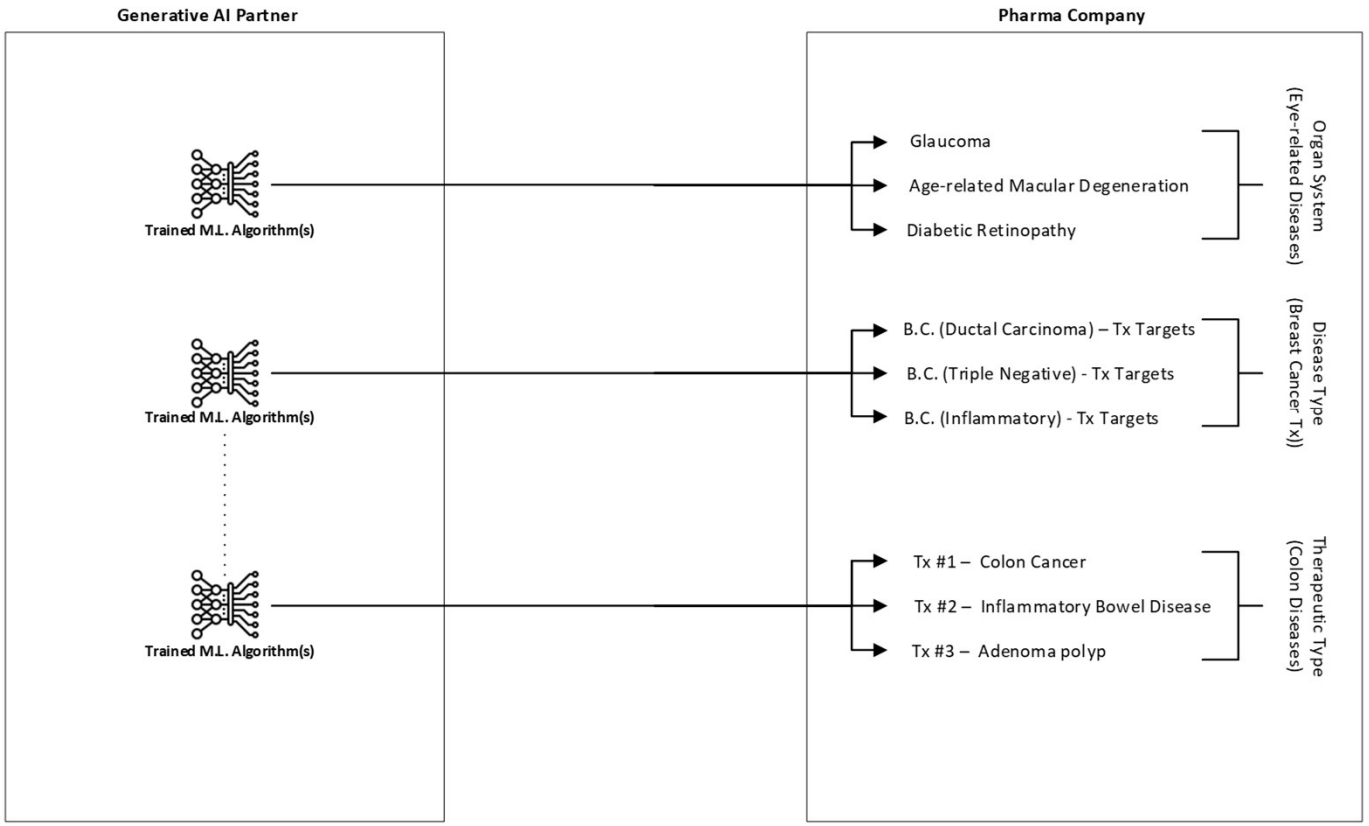
- Facts: Texas-based data insights company with cutting-edge proprietary AI/ML algorithms that can generate an array of insights and predictions, receiving data sets from a California hospital group, a Virginia-based Public genomic database, and a California University.

- What are the data regulatory considerations that must be addressed?
  - HIPAA: Applies to PHI obtained from **US Residents** by a **US Covered Entity or Business Associates**
  - California Consumer Privacy Act (CCPA)(CPRA): Applies to PHI obtained from **CA Residents**
  - Virginia Consumer Data Protection Act (CDPA): Applies to PHI obtained from **VA Residents**
  - California Genetic Information Privacy Act (GIPA): Applies to genetic data obtained by direct-to-consumer genetic testing companies from **CA Residents**

- Other considerations?
  - Field of Use
  - Ownership of insights
  - Primary and Secondary Rights
  - University Audit? RUO vs. Commercial Rights?

NRF

Data Use Scenario #5 – Data Map (Generative AI)



Data Compliance Scenario #5 (continued)

- Facts: Pharma Company contracts with Generative AI Partner with cutting-edge generative AI/ML tools that can generate an array of insights and predictions

- Any issues specific to Generative AI?
  - Added risks
    - No access or control of training data
    - No traceability of results
  - Risk management considerations

Bios

Roger Kuan

Partner
roger.kuan@nortonrosefulbright.com
San Francisco
T: +1 628 231 6810

Roger Kuan is the US head of the digital health and precision medicine practice and counsels companies that are uniquely positioned in the convergence of the life/medical sciences and technology industries on how to successfully navigate the complexities of the intellectual property (IP), data rights and regulatory challenges they encounter.

Roger has extensive experience in IP strategy and portfolio management (utility/design patents, trademarks, copyrights and trade dress), data rights strategy, licensing and technology transactions, freedom-to-operate clearances, enforcement, monetization, IP due diligence and dispute resolution. His practice is focused in the life sciences sector (e.g., research tools, analytical instrumentation/software, digital therapeutics, medical devices, diagnostics, biomanufacturing equipment, etc.) with an emphasis in emerging technologies such as Precision Medicine (e.g., genomic sequencing platforms, AI/ML, computational genomics/bioinformatics, molecular diagnostics, companion diagnostics, etc.), Digital Health (e.g., mobile apps, clinical decision support, software, digital therapeutics, AI/ML Imaging Diagnostics, wearables, etc.) and 3D printing/bioprinting.

Earlier in his career, Roger served as Director, IP Counsel at a multinational biotechnology company, where he managed a team to support the worldwide IP needs of the company's life sciences tools, bioproduction, molecular diagnostics and nucleic acid sequencing system/software platforms. Prior to finishing his law degree, he worked in the life sciences industry for several Fortune 500 pharmaceutical, medical device and chemical companies. He has held professional positions in the R&D, sales, engineering and regulatory affairs organizations.

Jason Novak

Partner
jason.novak@nortonrosefulbright.com
San Francisco
T: +1 628 231 6811

Jason Novak is a Partner in Norton Rose Fulbright's Precision Medicine and Digital Health Practice Group, where he focuses on advising entities, both large and small, on the various legal issues that can arise with emerging technologies in the healthcare and life sciences industries. Tech and Biotech are traditionally disparate technologies that, when blended together to form many of our most exciting new technologies, bring forth a combination of unique and interrelated legal issues.

Jason has extensive experience in IP strategy and patent portfolio management, preparation and prosecution, oppositions, counseling, licensing and technology transactions, in and out-licensing, freedom-to-operate, various types of due diligence, IP training, risk recognition and management, and dispute resolution. He directs that experience to clients in various industries, particularly in the medical device, microfluidics, personalized/precision medicine (e.g., genomic sequencing platforms, computational genomics/bioinformatics, and molecular diagnostics), digital health, life sciences tooling, and food industries.

Prior to starting this practice, Jason was a IP Director for Thermo Fisher Scientific, where he managed worldwide IP needs in genetic sciences instrumentation and software (e.g., qPCR, dPCR, capillary electrophoresis). Jason managed large IP portfolios, a team of agents and attorneys, licensing programs, various diligence needs, various IP-related transactions, and foreign and domestics patent challenges.

Before moving into the legal industry, Jason was a research engineer for a leading food product company, where he led numerous product and process redesigns, reformulations and launches. This cross-functional role required interaction and experience with operations, finance, marketing and regulatory areas, contributing to Jason's ability to deal with various corporate functions from both an R&D and legal perspective.