

An Introduction to Quantori's Registry Science and Quantori's Practice



QUANTORI

Who is Quantori?

Combination of Informatics, Registry Science Expertise, Analytics, Combined with Best-in-Class Engineering



Experienced
management

750+

Experienced software engineers, data scientists, and applied
mathematicians with life science domain expertise



Blue-ribbon
List of clients



Life science platforms, applications,
and tools/ industry awards

**Proven expertise and track record of
successful application construction,
implementation and execution for not-for-
profit and Life Sciences organizations**

Quantori: a snapshot



Our Mission

We combine our deep scientific knowledge and pharma digital platform know-how with data science expertise and agile software engineering to help our clients accelerate the development of novel treatments that improve patient lives and advance human health.

Our 650+ member team has experience in the Life Sciences industry domain is complimented with a strong understanding of the principles of regulatory approaches and management of data globally in the US and Europe, as well as the technologies involved.

Major Concentrations & Specialties

R&D and Early
Solutions Innovation IT

Scientific Informatics
and Data Sciences

User-Centric Design,
UX & UI

Data Insight &
Advanced Analytics

Product Management &
Digital Platform
Engineering

HPC & Cloud
Infrastructure
Enablement

What is Registry Science?

Definition

The procedures, data science and overall capability needed to generate, maintain, and analyze highly specialized, highly curated, multimodal longitudinal data to better define the journey of the study subjects to track long-term outcomes for both clinical and regulatory needs.

Registry science includes not only technology but the following:

- Data and Regulatory Governance
- Security and Privacy
- Technical build and platform
- Long-term data storage and analytics strategies
- Engagement Strategies to maintain longitudinal interactions with participants
- Returning value to participants (when appropriate)
- Returning insights & value to sponsors
- Informing data-driven clinical care decision making
- Safety monitoring (for clinical registries)

Organizations that find value in creating registries (examples)

Pharmaceutical
Companies

Basic Research
Organizations

Rare (orphan) Disease
Research Foundations

Data Insight & Advanced
Analytics firms

Patient Advocacy
Organizations

Medical Device
Manufacturers for long-
term safety/efficacy

Healthcare Provider Orgs
that need to benchmark
practices

Gov't Agencies that need
to track epidemiology of
specific diseases

Any healthcare, business, or government organization that needs to track longitudinal data from multiple sources can benefit from the highly curated nature of data generated by a registry

Typical Use Cases for Registries (examples)

Direct Clinical Care

Safety (AE/SAE)
Monitoring

Clinical Decision
Support

Quality Improvement/
Learning Health
system

Patient Self Care

Disease Monitoring
/ Epidemiology

Policy Support &
Benchmarking

Basic Science

Disease
Communities /
Journeys

Patient Advocacy

Regulatory
Requirements

Observational
Studies

Collecting well curated, longitudinal data remains a common thread for registry use cases

Why a Registry vs EHR/EMR?

EHR

- Broadly focused on episodic patient care
- Optimized for patient care and billing
- Generally not geared as a research environment
- Little effort to deal with missing data
- Data types used in clinical care - research data types may not exist
- Episodic care is supported
- Collection on a specific problem not assured
- If patient leaves network or healthcare systems, due to disconnected nature of healthcare, data from other providers may or may not be part of the record
- Production systems across the US have limited interoperability - roll-ups are exceptionally difficult

Registry

- Highly focused on a specific condition, problem, or area of research
- Longitudinal data collection is its raison d'être
- Primarily used for tracking longitudinal trends on very focused questions
- Multimodal data types (research data) often needed and supported (eg: genomics, proteomics or other "omics")
- Can be focused as research or commercial venture (or a blend)
- Can be self-sustaining fund itself by monetizing data assets
- Highly curated for completeness

Registries provide focused, long-term data capabilities that are not generally possible with EHRs

Contrasting Two Registry Approaches (as examples)



Research-centric

- Usually institution-centric
- Main end-user: researchers, clinicians
- Data usually not be used for clinical purposes
UNLESS labs or assays run in CLIA mode
- Highly agile, ability to use data nearly immediately
- Always done with oversight (IRBs)
- Often do not share data with patients
(less complexity)
- Usually grant funded - does not monetize data for sustainability
- Patient recontacting not usually a focus

Patient-Centric

- Main focus is on the patient - Patient gets data back from registry
- Can bypass academic organizations
- Can be an “all-comers” strategy (anyone in the country)
- Provides focused data/information/knowledge back to the patient in addition to other stakeholders
- Can grow beyond the focus of one or a few institutions.
- Long-term patient engagement critical for success
- Consent for re-contacting possible
- Can monetize data for sustainability

There is no “right answer” - the choice of “kind of registry” is dependent on the use case

Our Registry Science Expertise at a Glance: Data and Analytics Excellence



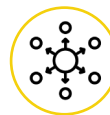
Overview: With over two decades serving the Pharmaceutical & Life sciences industry, Quantori services support end-to-end to create best-in-class registries.



Lab / Digital Lab
data integration



Inclusion of Multi-Omics &
Sequencing Data types



Integration of decentralized
adjacent data types



AI/ML & HPC
Enabled Registry
Overlay (where
appropriate)



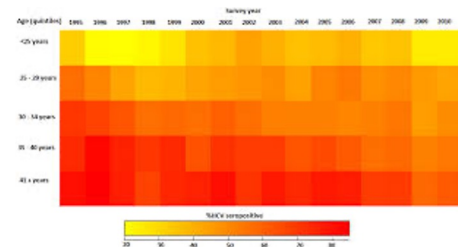
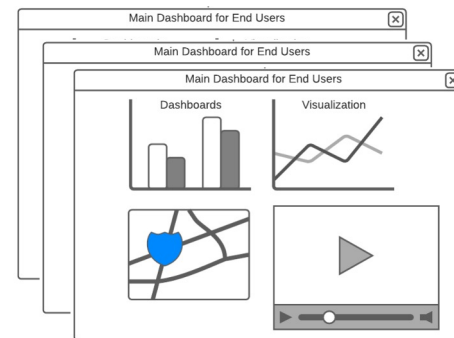
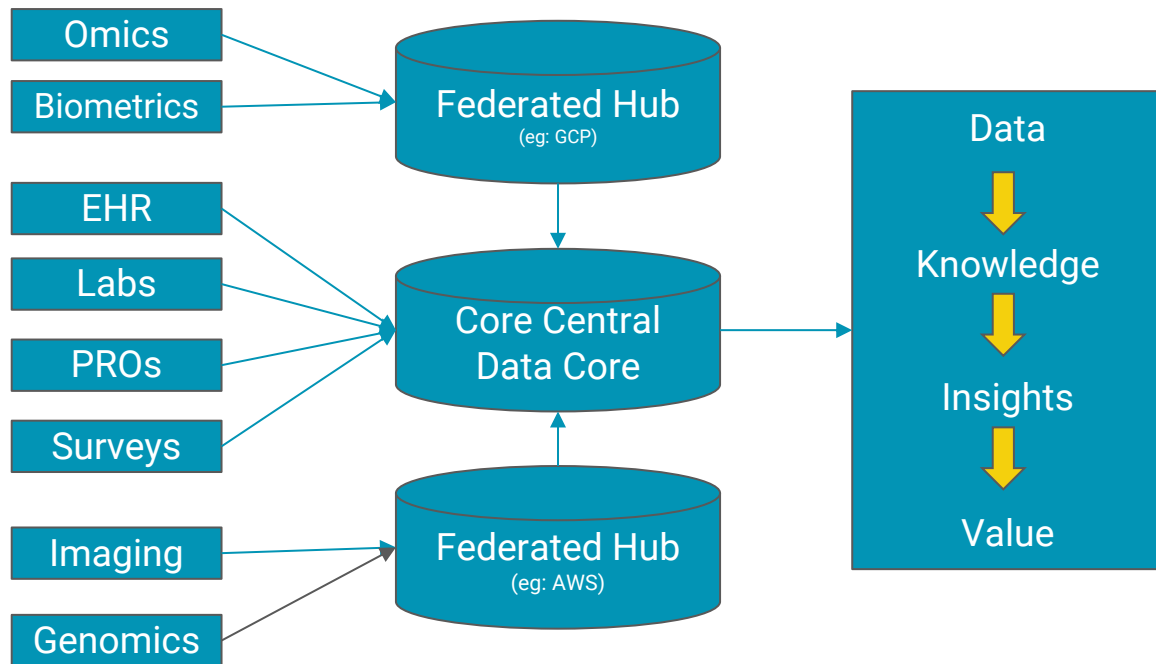
Data strategies
including
monetization for
sustainability



Insight generation for patients,
caregivers, clinicians, and
researchers

Quantori focuses on the creation of multi-modal, longitudinal data sets for both research and clinical use.

We Build Workable, Reliable Methods & Means to Create Focused Data For Researchers, Clinicians and Patients



Novel Data Visualizations

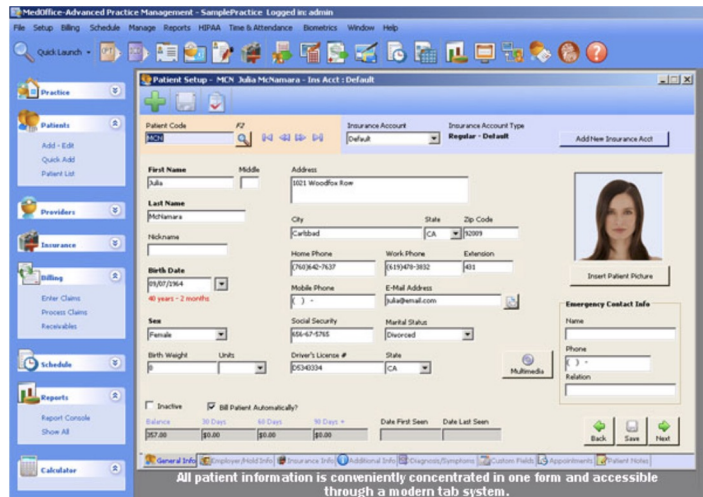
Quantori not only constructs best-in-class systems, but the means to analyze the resultant data

Descriptive Characteristics of Example Registries

	MMRF CureCloud	ASH	Follicular Lymphoma (in process)	Food Allergy	Hackensack COVID	CFF's Port CF
Focus	Individual PatientsE	De-identified Patients	Individual Patients	De-identified patients	De-identified patients	Identified Patients
Longitudinal						
Clinical Data entered by	Abstraction, Ingestion	EHR ingestion, abstraction	TBD	Patient Survey	EHR abstraction	Clinician-entered
Patient Surveys						
Clinical Data (eg: EHR)						
Genomic						
Immunologic						
Claims						
PROs						
Direct to Patients						
Direct to Researcher						
Data used for monetization?						

Data Entry Considerations: How to get data into the system?

- Do the pre-work on a standardized data dictionary and data model
- Consistent Entry
 - Manual Data Entry - eg: CRF
 - Automated data entry - eg: EHR ingestion
 - Semi-automated ingestion - eg: encoded anonymized matched data entry - such as adding genomic sequencing
 - A combination of the above
- Ensure system can handle metadata - or add it on
- If considering EHR data, think twice - it's harder than it sounds in 2021
- Regardless of the approach, you need to have good data governance principles in place for checking the data integrity on entry



The screenshot displays a web-based application titled "MediOffice - Advanced Practice Management - SamplePractice". The interface includes a top menu bar with options like File, Setup, Billing, Schedule, Manage, Reports, HIPAA, Time & Attendance, Biometrics, Window, and Help. A left sidebar contains navigation icons for Practice, Patients, Providers, Insurance, Billing, Schedule, Reports, and Calculator. The main content area is titled "Patient Setup - MEN Julia McManara - Ins Acct: Default". It contains a form for entering patient information, including fields for Patient Code, Insurance Account, First Name, Last Name, Address, City, State, Zip Code, Birth Date, Sex, Social Security, and Driver's License. There are also sections for Emergency Contact Info and a "General Info" tab at the bottom. A footer note states: "All patient information is conveniently concentrated in one form and accessible through a modern tab system."

The MMRF's CureCloud

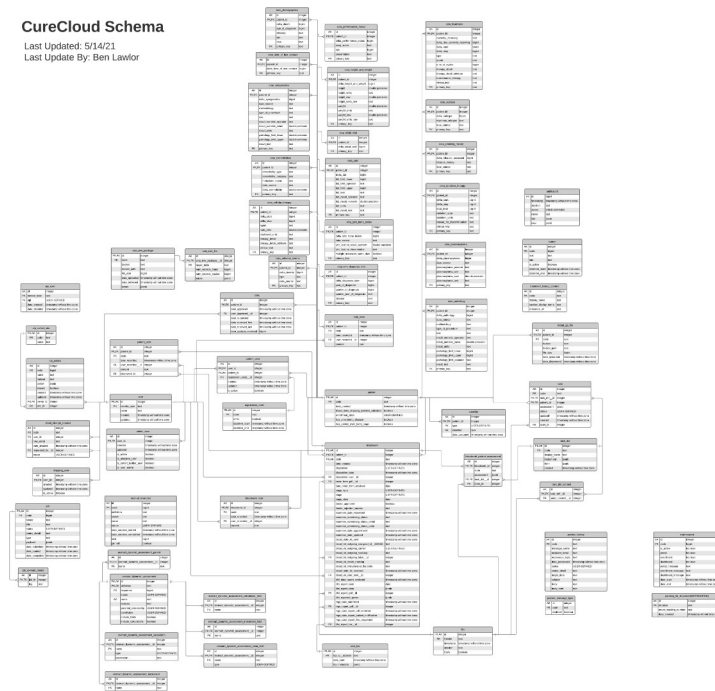


The MMRF CureCloud is a Direct-to-Patient Registry with the following goals:

- Create the most comprehensive data set for multiple myeloma for patients, clinicians and researchers
- Democratize data from the system by returning data to patients
- Create an analytics platform to generate best-in-class studies of the mixed data from the system to find new cures
- Create a monetary stream to help sustain the system
- Recruit 5000 patients into the system over the next 5 years - run the system for a minimum of 10 years

CureCloud Schema

Last Updated: 5/14/21
Last Update By: Ben Lawlor

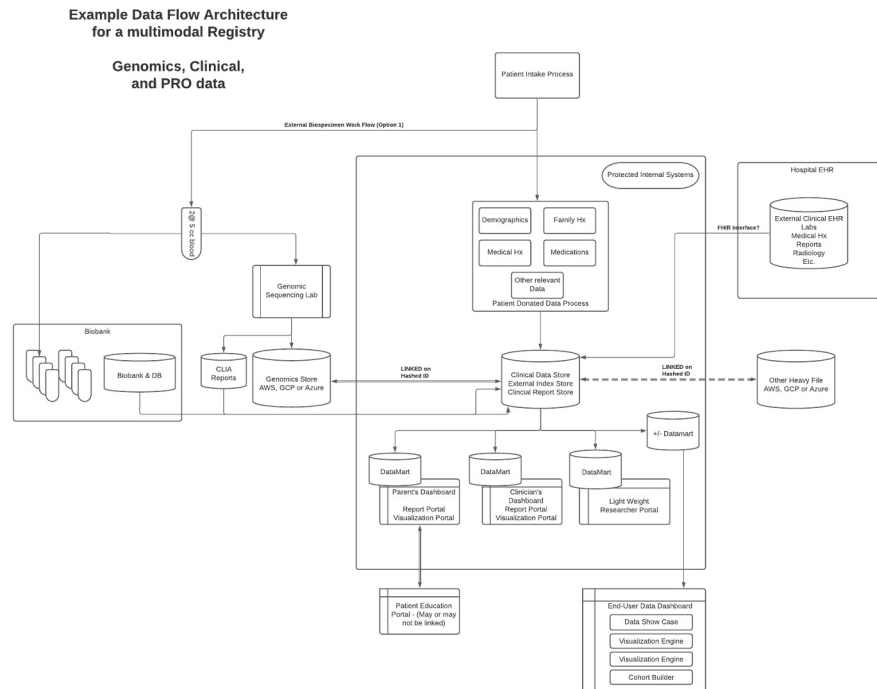


A sample high-level architecture for a multi-modal registry



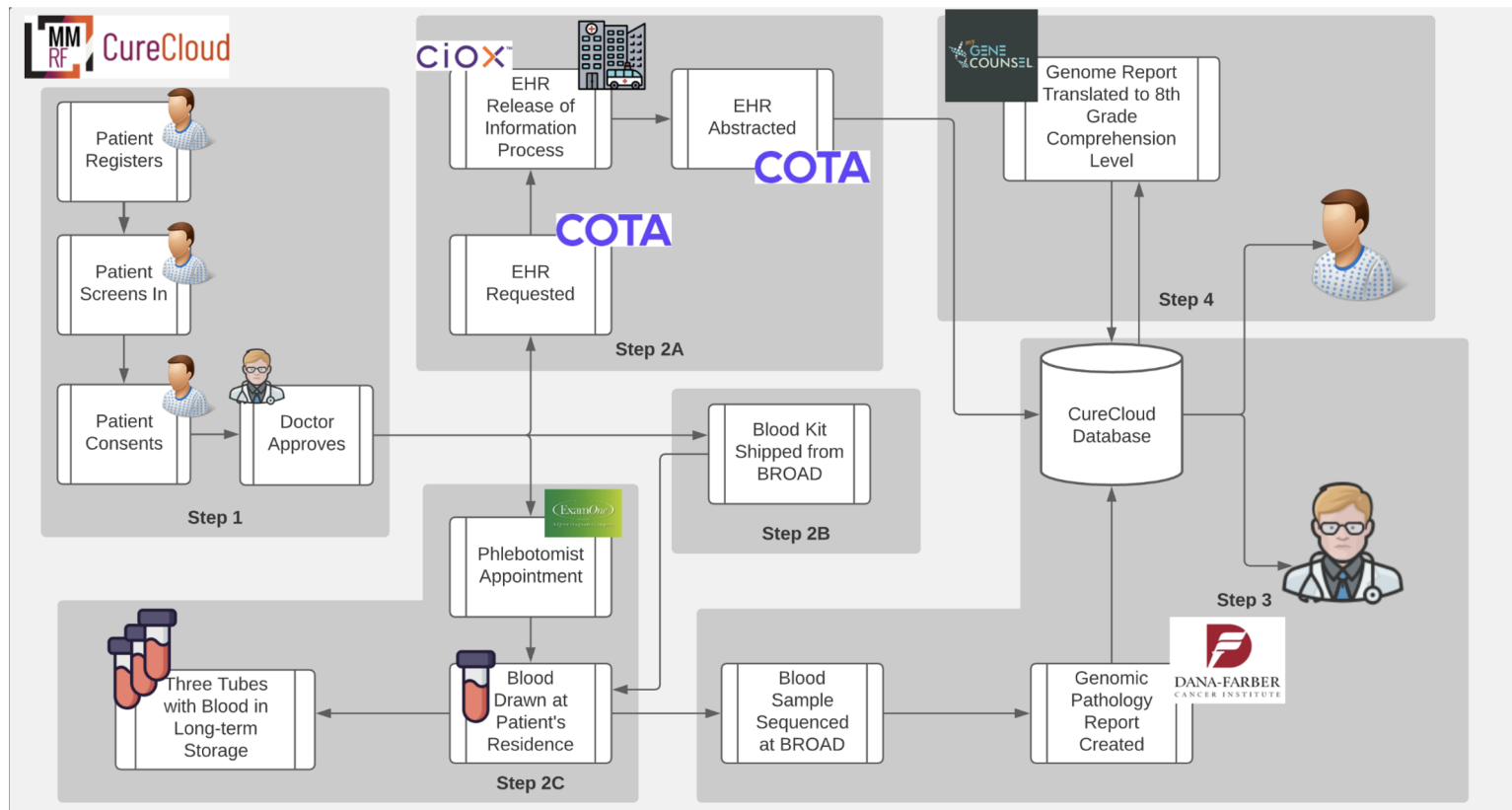
This system assumes:

- Direct-to-patient Registry (patient “front door” for data donation)
- Data types
 - EHR data
 - Genomic Data (returned to patients)
 - Proteomic
 - PROs
- Data Visualizations for patients, clinicians and researchers
- Use of a tissue bank

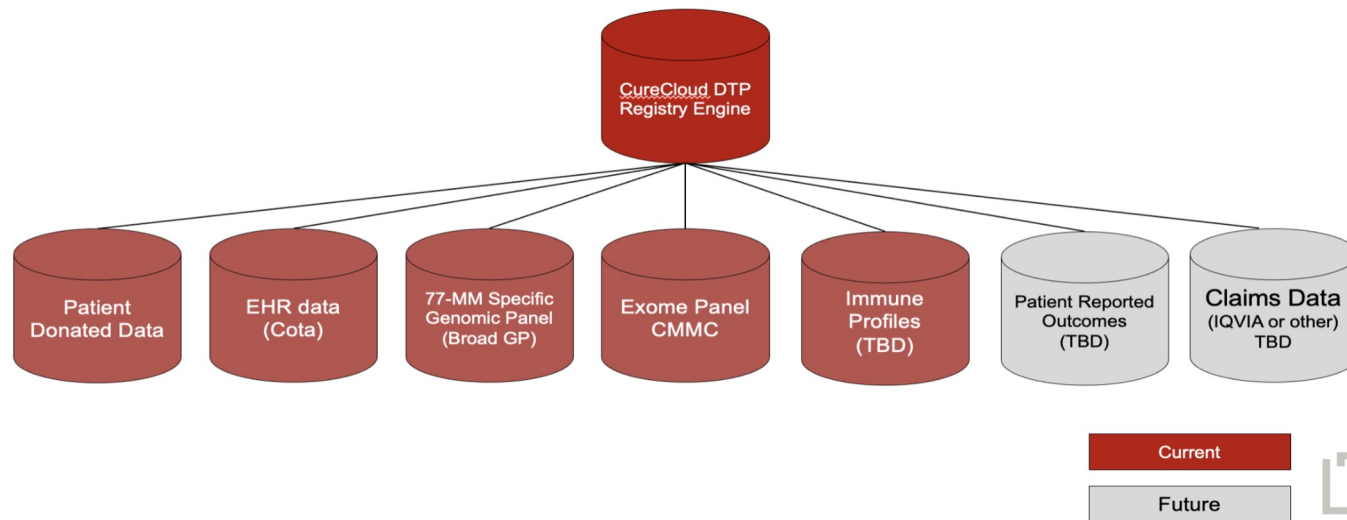


Quantori not only constructs best-in-class systems, but the means to analyze the resultant data

The CureCloud Workflow



The CureCloud Registry



Quantori's Registry Science Team



Dr. Steven Labkoff

Global Head, Clinical & Research Informatics

30+ year career in life sciences, informatics, medicine, RWE, biomarkers, clinical trial decision support

Chief Data Officer at Multiple Myeloma Research Foundation - stood up largest myeloma registry in the world

Senior leadership roles at AstraZeneca and Pfizer

Training: Postdoc Medical Informatics, Harvard Medical School & MIT



Dr. Yuriy Gankin

Chief Scientific Officer

Co-founded GGA Software Services
Served as GGA Chief Scientific Officer

Served as Chief Life Sciences Officer at EPAM
PhD in Analytical Chemistry from Tufts and EMBA from MIT Sloan School



Richard Golob

Chief Executive Officer

Co-founded GGA Software Services
Served as GGA CEO

Served as Global Head, EPAM Life Sciences Business Unit

Built EPAM Life Sciences into company's fastest growing division

AB in Biochemical Sciences at Harvard College