Unleashing Data's Full Potential through Integrated Data Marts

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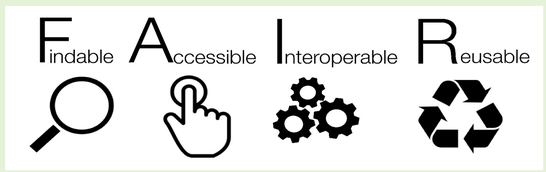
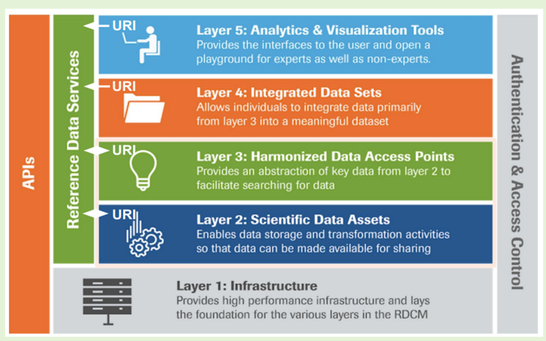
Background: Giving Data a Second Life with Roche Data Marts

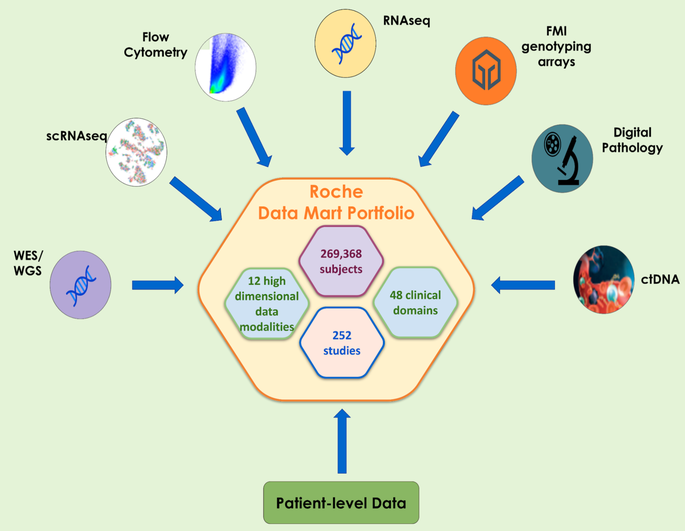
Aim: leverage Roche's large pool of existing patient data to generate insights, improve diagnostics, and drive R&D.

- To achieve that goal, the data must be **F**indable, **A**ccessible, **I**nteroperable, & **R**eusable (FAIR).
- At Roche, FAIR-ification and integration of multi-modal data is done within the **E**nhanced **D**ata and **I**nsight **S**haring (EDIS) department.
- Clinical and high-dimensional biomarker data are integrated into **M**ulti**A**ssay**E**xperiment (MAE) objects.
- Collections of MAEs for a given indication make up a single data mart.





Challenge: Integrating Diverse Data Types into Data Marts



- Standards must be established with vendor/data providers
- Evolving data models and specifications
- Lack of standardization between datasets
- Constantly evolving processing pipelines
- Data collected under very specific experimental conditions
- Inadequate capture of relevant metadata

Solution: Standardized Workflow for Diverse Data Types

Workflow for Streamlining Integration of New Data Types

0 **Engaged, early discussions with vendors to align on file format specifications: data content, output format, metadata, etc.**

1. **Biological understanding of novel data type** — Understanding of data & data exploration
2. **Evaluation of analysis potential** — Understanding of potential analysis insights and impact on clinical decision making
3. **Development of data model & specifications** — Proof of concept: development of a data model inspired by industry trends, analyst review and refinement
4. **Implementation in another therapeutic area** — Knowledge sharing with other teams, further refinement
5. **Consolidation in R package** — Data type wrappers and functions consolidated in an R package

Case Study: Integration of Global Screening Array Analyses

Global **S**creening **A**rrays (GSAs) are a faster, more cost-effective alternative to traditional **W**hole **G**enome **S**equencing (WGS). When GSA data was introduced into the data marts as a novel data type, the workflow described here was put to the test:

- Developed a **data model for raw data and each analysis product** (HLA genotyping, Polygenic Risk Scores, etc) to fit the MAE integration workflow.
- Working with data providers and upstream/downstream analysts, **refined the data model to serve all stakeholders.**
- Collected all **relevant metadata** supporting the data providence to include in the integrated object.
- Subject matter experts developed **in-depth documentation** to relay pertinent information to future integrators.
- Generated **quality control scripts** to test subject-to-sample mapping, completeness of the data, and accuracy of the data.
- **Timeline improvement:** Initial data objects were developed in approx. 3 months from the time the data could be accessed until final **S**ummarized**E**xperiments (SEs) were delivered. Now, it takes around a week to generate 168 SEs for a given data type across 28 studies for one indication/data mart.

Implementation: Each Data Mart is a Collection of Study Level MAEs Across an Indication

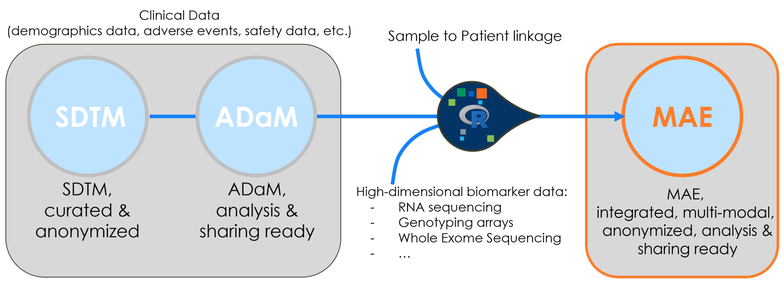
Importance of a data model for streamlining integration

- Central to the Roche internal R landscape
- Developed by the R/Bioconductor community
- Container for patient-level & high-dimensional data modalities
- In-build systematic, consistent metadata
- Standardization by design
- Consistent input for downstream storage & analyses platforms

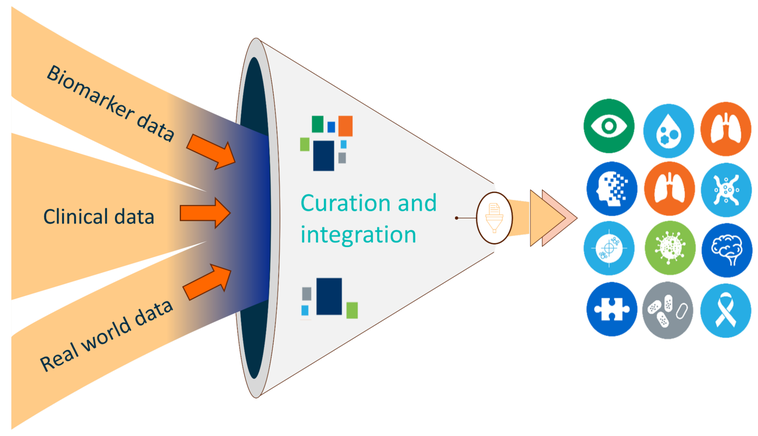
⇒ MultiAssayExperiment as a unique, self-sufficient data model

Data Marts are Delivered as 3 Data Models

Each data mart consists of a set of SDTMs, ADaMs and MAEs



The MAEs (MultiAssayExperiment objects) are multi-dimensional R objects that contain clinical (ADaM) and biomarker (omics) data. They are anonymized and available for sharing.



Lessons Learned: Overcoming Challenges of Multi-Modal Integration

The only sustainable way to manage the volume of data encompassed in the data marts is to harmonize inputs, standardize deliverables, and automate workflows across the entire end-to-end engine.

Recognizing roadblocks at the very beginning of data curation and integration can **help avoid errors**, **improve secondary data re-use**, and **enhance workflow automation**.

Potential Roadblocks:

- Non-unique sample identifiers
- Unexpected changes to upstream data outputs
- Storage size concerns
- Subtle differences between data models can impact ability to automate
- Deprecation of old data models
- Communication between multiple teams across the organization

Future Directions: Where can we go from here?

As the integration workflow becomes more automated, focus is beginning to shift to **development of visualization and analysis tools** to make the data even more accessible. **Additional data marts** will be released for high priority indications including **additional data types**. Further **infrastructure development** is also underway to solve lasting issues with data storage and retrieval. Finally, end user **support, training and tutorials** are onging to ensure the data can be used to its fullest.

Impact: Doing Now What Patients Need Next

The Roche organization's entire data landscape is working to become FAIR. Since 2020, **20 Roche EDIS data marts** have been deployed. The FAIR data included in these data marts has enabled **54 key R&D insights, allowing for faster access to data, efficient streamlining of the end-to-end engine, and cost-savings for the company**. A **single insight can lead to numerous impacts for the company**, including risk-reduction, patient safety, informed trial design, accelerated timelines, new commercial opportunities, scientific innovation, and increased revenue/savings. Additionally, the end-to-end engine has resulted in **significant critical path reduction** by shifting the focus from study level to indication level data. Many processes are suitable for **automation, resulting in a drastic decrease in resourcing needs**. Given these statistics, it is estimated that the data marts have **saved millions** for the company's end-to-end R&D engine.

FAIR data's impact for

- ✓ **Patients**: Making the most out of the patient data that we are entrusted with.
- ✓ **Teams Across the Roche Organization**: Data are more standardized and accessible, and shared in a FAIR way, generating insights far beyond what any one study team could generate.
- ✓ **Business**: Standardized data enables **faster insights**. Access to **consistent** data across indications means that R&D decisions can be made quicker and more accurately, saving money on development and generating revenue faster.

Acknowledgements

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