

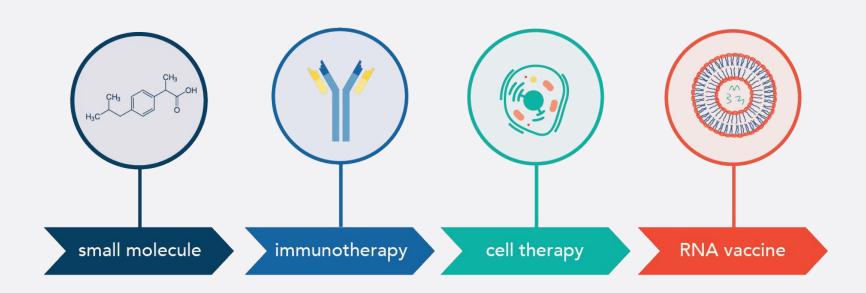
### Designing for life and death decisions

Building data products for biopharma operations

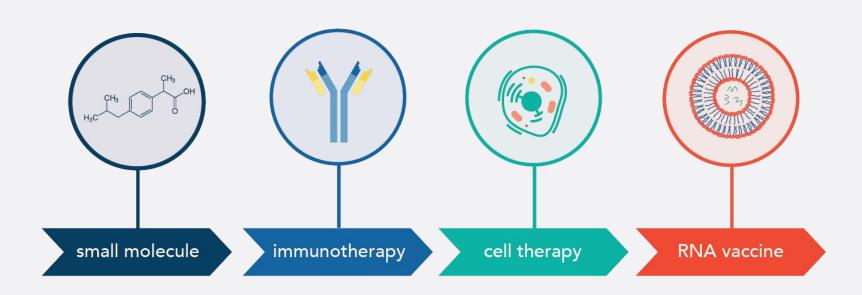
#### **Clare Gollnick**

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PhD, Biomedical Engineering

#### Simplifying Access to Biomanufacturing Data



#### Is this batch of drugs safe for release to patients?



Data is objective. (?)

Data can sometimes be objective,

Data can sometimes be objective, if all stakeholders agree on the objective.

# Agreeing on the benefits is not enough. Stakeholders must also agree on the **cost of failures**.





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Data is a tool for

different stakeholders to meet different objectives.

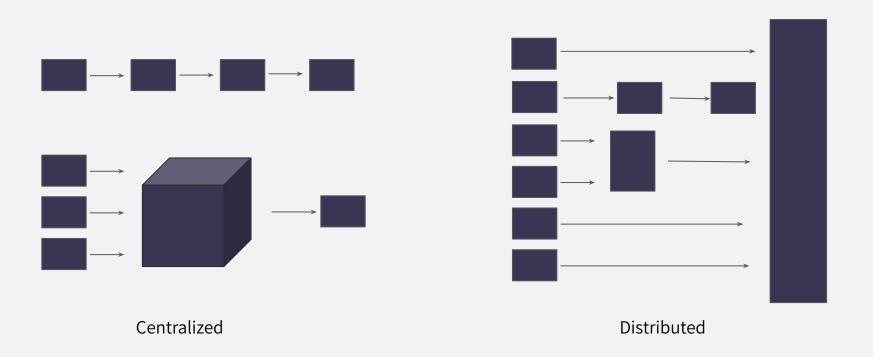
#### Data cleaning algorithms should:

✓ Fail visibly, often intentionally

Be auditable and correctable

✓ Allow for multiple perspectives

Fail Intentionally: Distributed pipelines limit the blast radius if an edge case causes an unexpected error



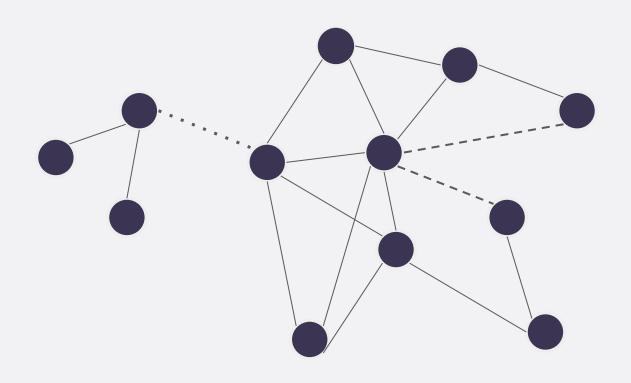
## Be Auditable: A layered data model allow experts to make domain-specific corrections



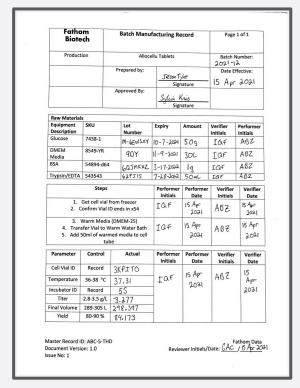


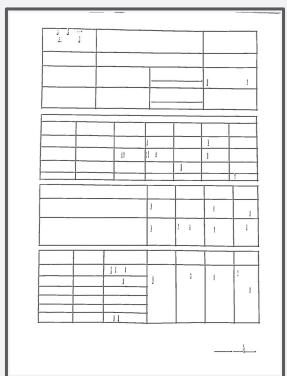
"Floating Garden (空中庭園展望台" by wkc.1 is marked with CC BY 2.0.

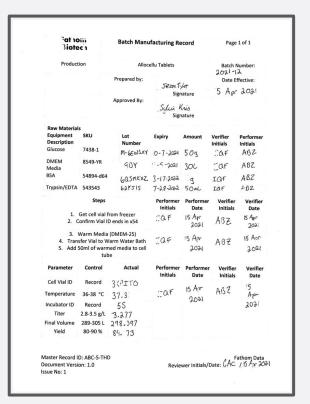
Support Multiple Perspectives: Graph-based data model allows dynamic reconstruction of different world views from the same data



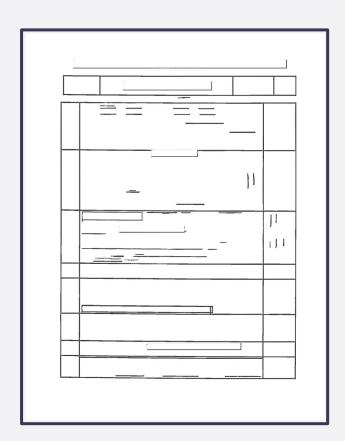
#### Biomanufacturing batch records modeled as layers

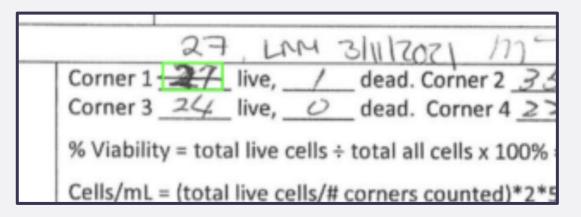






### Manufacturing Science vs. Quality: Is a cross out still data?





#### Fathom's perspective on data and data architecture

- Data is a tool to achieve a specific objective. It is not inherently objective.
- Algorithms always make mistakes. Data products should reflect that.
- Understanding the cost of a failure is often a foundational product question.
- Be open to keep multiple copies of the same data it's just different perspectives on the same world.