

# Data Integrity in the Personalized Medicine Journey

Fast, patient-specific treatments like mRNA vaccines require unique data management.

What are the specific requirements for data integrity in personalized compared to traditional medicines?



## 01. Patient Sample Collection

### Challenge 1



#### Need for Speed

Weeks, not months, demand rapid data & audit trail reviews

### Challenge 2



#### Bridging Teams

Bioinformatics & Quality must align via training & awareness

### Challenge 4



#### FAIR Principles

Ensure data is Findable, Accessible, Interoperable, Reusable



## 02. Bioinformatics & Manufacturing

### Challenge 3



#### Batch Complexity

Numerous data exchanges need clear QA agreements

### Challenge 5



#### AI/ ML Integration

Requires modern QMS integrating CSV, DI & ML validation



## 03. Vaccination

### Challenge 6



#### Regulatory Navigation

Uncertainty remains