Genomics England
The importance of, and how to approach, standards – A working example
How did it all start?

• NHS England required Genomics England to be certified to ISO 15189.

• Work commenced around July 2017.

• Certificate was awarded in March 2019.
Key Elements of the QMS for Certification

- Management Responsibility
- Audits
- Documentation: Quality Manual, Quality Policy, SOPs
- Training
- Interactions with other Teams
- System to store documents
- Management of Deviations, Non-Conformities, Clinical Incidents, and Complaints
- Clinical teams, Service Desk, Development and Testing

- Monthly Quality Committee Meeting
- Annual Management Review Meeting
- Internal audits
- Supplier Audits
- Audit reports and follow-up

Identify types of Training Competency requirements and assessments.
Benefits

Bringing the Executive Leadership on board.

Structured approach with documented procedures for added consistency.

Better handling of non-conformities and subsequent CAPA management.

The standard forces good practices.

Performance measurement against KPIs
Challenges

• Transitioning from a research/academic environment to a more structured environment

• Mixture of skills – software development, research, technology- documentation is not the priority.

• Certification timelines due to the unique nature of the work done.

• Having a system that pleases all is near impossible.
Challenges

• Having good reference material/standards to benchmark against - specific challenge of rare disease where the causative variant may never have been seen before.

• Ongoing EQA schemes.

• Challenges around software versioning.
The Future – Looks exciting.

ISO 15189

Maintaining this and extending the scope

ISO 13485 certification

Defining and developing the regulatory pathway for Whole Genome Sequencing

CE marking

Research Environment and Quality of Data

Defining pragmatic controls around this
## The Future Certification to ISO 13485

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Thank You.

Questions?