Blueprint Genetics

Akkreditointi kilpailukyvyn mahdollistajana

FINAS-päivät / Akkreditointi mahdollistajana / tammikuu 29, 2019 / Olli Mikkonen

Agenda

- Introduction to Blueprint Genetics
- Accreditation and regulatory compliance
- Accreditation as driver to increase organizational excellence
- Accreditation and competitive advantage

We are developing groundbreaking solutions that take genetic testing to mainstream healthcare – to benefit patients with rare inherited diseases worldwide.

High quality genetic diagnostics for a global clinical community

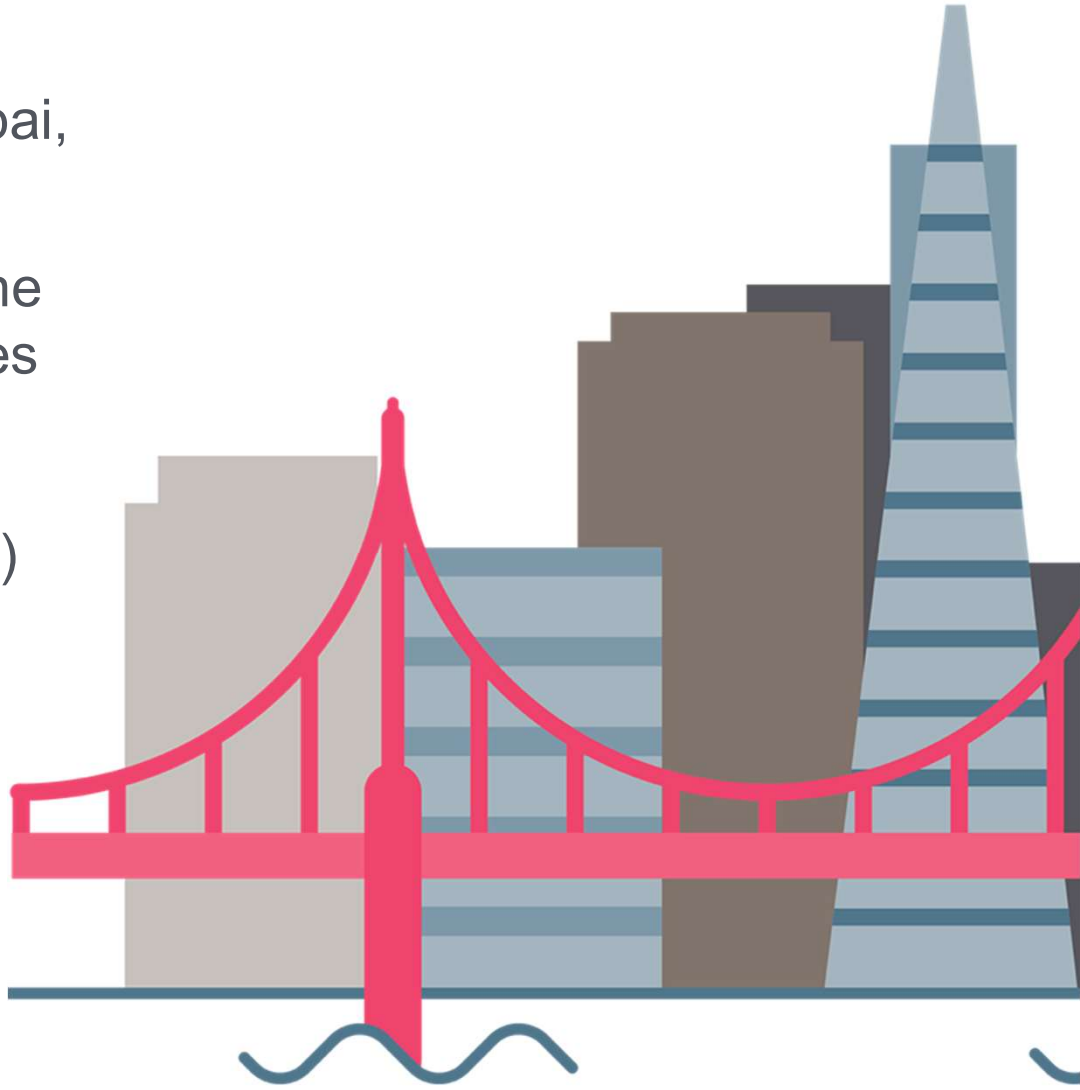
- Estimated 350m people globally affected by rare diseases
- Efficient diagnostics provides a faster path to the treatment of patients

- Diagnostics for 14 medical specialties
- Over 220 diagnostic panels
- Results in 3-4 weeks

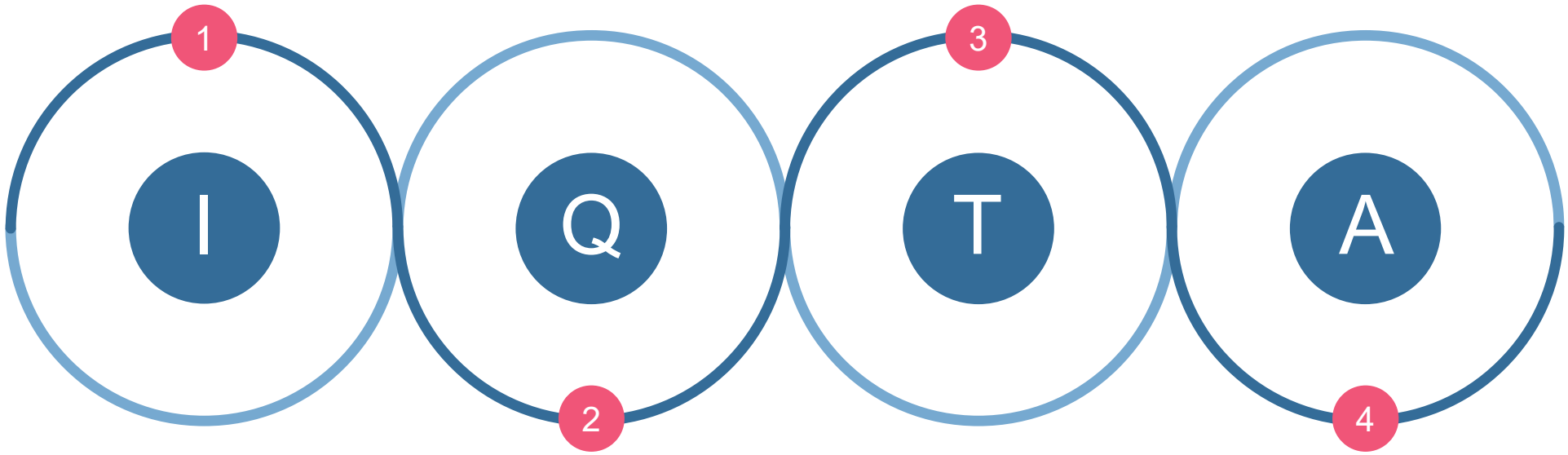
Blueprint Genetics

Background

- Offices in Helsinki, San Francisco and Dubai, personnel in 12 countries
- Key markets USA, Canada, Nordics and the Middle-East, customers in over 40 countries
- Number of employees: 140
- Revenue: €8.9 million in 2017 (3.1 in 2016)
- Accreditations: ISO 15189 (FINAS), CAP
- Certifications: CLIA + US states
- Founded in 2012



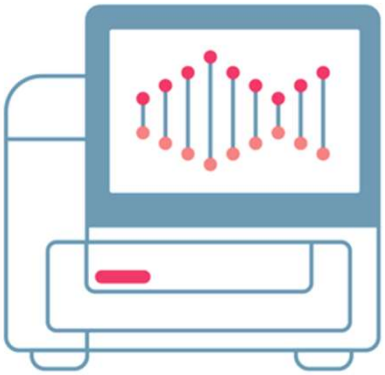
4 guiding principles



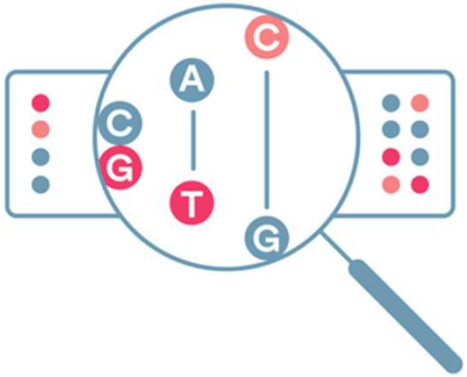
Our process

Patient sample

DNA sequencing

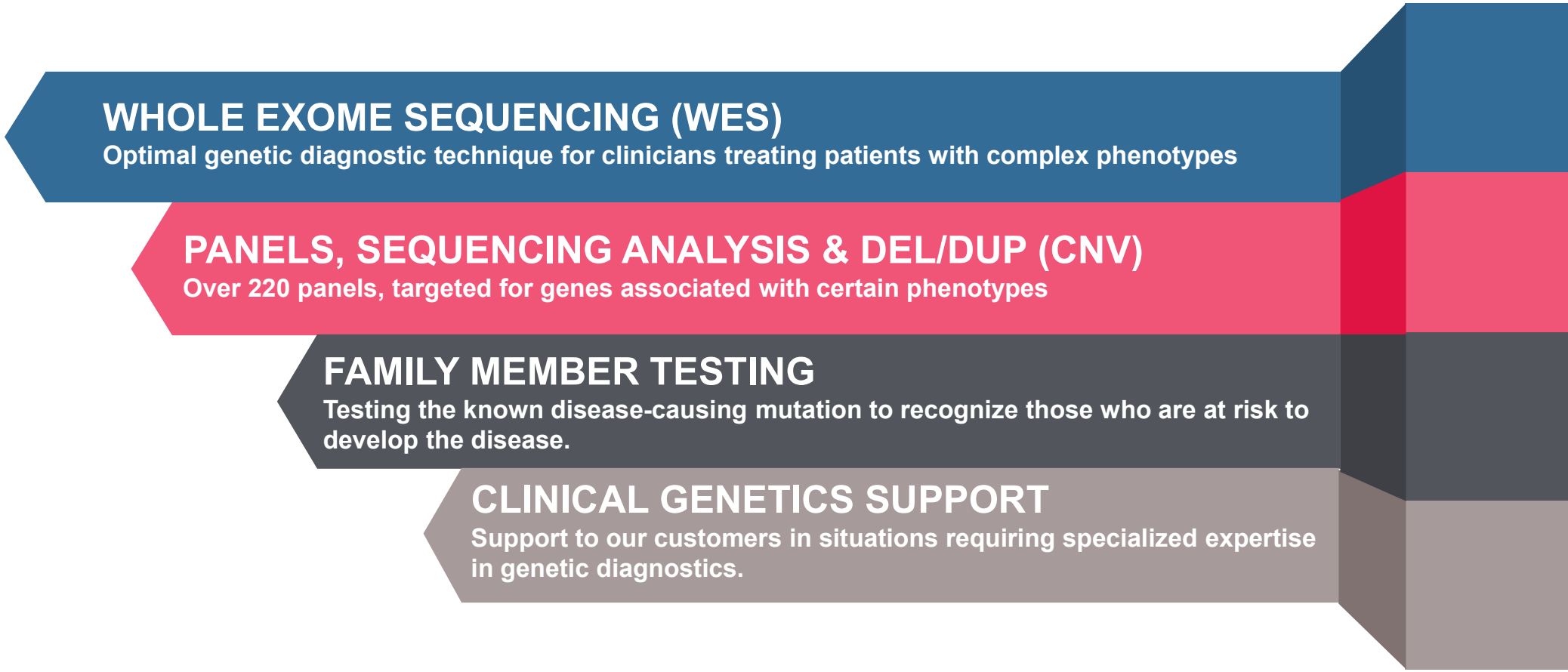


Analysis and interpretation



Clinical report

What we do



All our panels are based on our high-quality whole exome sequencing data.

Regulatory compliance

- Compliance with regulations = “freedom to operate”
- BpG operates on a heavily regulated field

Clinical laboratory	IVD medical devices	Privacy, personal data
• ISO 15189 • CLIA + US states • CAP (College of American Pathologists) (US)	• IVDD / IVDR (EU) • FDA LDT (US)	• GDPR (EU) • HIPAA (US)

Regulatory compliance with ISO 15189 accreditation

- Clinical laboratories
  - France: All clinical labs, either public of private, must be accredited by 31 October 2020
  - Germany: Formal accreditation is not mandatory but it is expected that clinical laboratories follow German Medical Association: Guidelines of the German Medical Association for Quality Assurance in Medical Laboratories (“RiLiBÄK”) which is regarded as state-of-the-art by justice. RiLiBÄK is based on ISO 15189.
  - UK: Proposal in 2008 "that all pathology service providers should be subject to mandatory accreditation by an organisation independent of the providers and the professions.". Current status in March 2017, approximately 75% of laboratories had been assessed to this standard, with the expectation that 100% of laboratories will have been assessed by March 2018.
- IVD Regulation (2017/746) and health institutions
  - For the in-house manufacturing by health institutions, article 5(5) requires
    - “an appropriate quality management system” and
    - “the laboratory of the health institution is compliant with standard EN ISO 15189”

Regulatory compliance with ISO 15189 accreditation case ”GDPR”

- *How are ISO 15189 and GDPR related?*
  - *Besides e.g. subclauses 4.1.1.2e, 5.2.2a and 5.10.3g*
- On May 25nd 2018, the General Data Protection Regulation became enforceable. To comply with the regulation, we needed to define and design new and improve existing internal processes.
- Because we already had the *quality management system* up and running, process improvements were straightforward to implement.
- Moreover, thanks to the effective QMS, GDPR-related activities such as conducting DPIA can be done efficiently and in a correct way every single time without wasting time and resources.

Conclusion: ISO 15189 based QMS helps us to introduce new processes

Accreditation and organizational excellence

- Compliance is a starting point but just being compliant does not itself generate any income, but customer focus and providing superior value do!

Ultimate goal

meet (exceed) the expectations of Blueprint Genetics' customers and provide superior value to them

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Achievable when our operations are

efficient and effective

i.e. we are able to provide consistently accurate results in a timely manner with the most judicious use of resources

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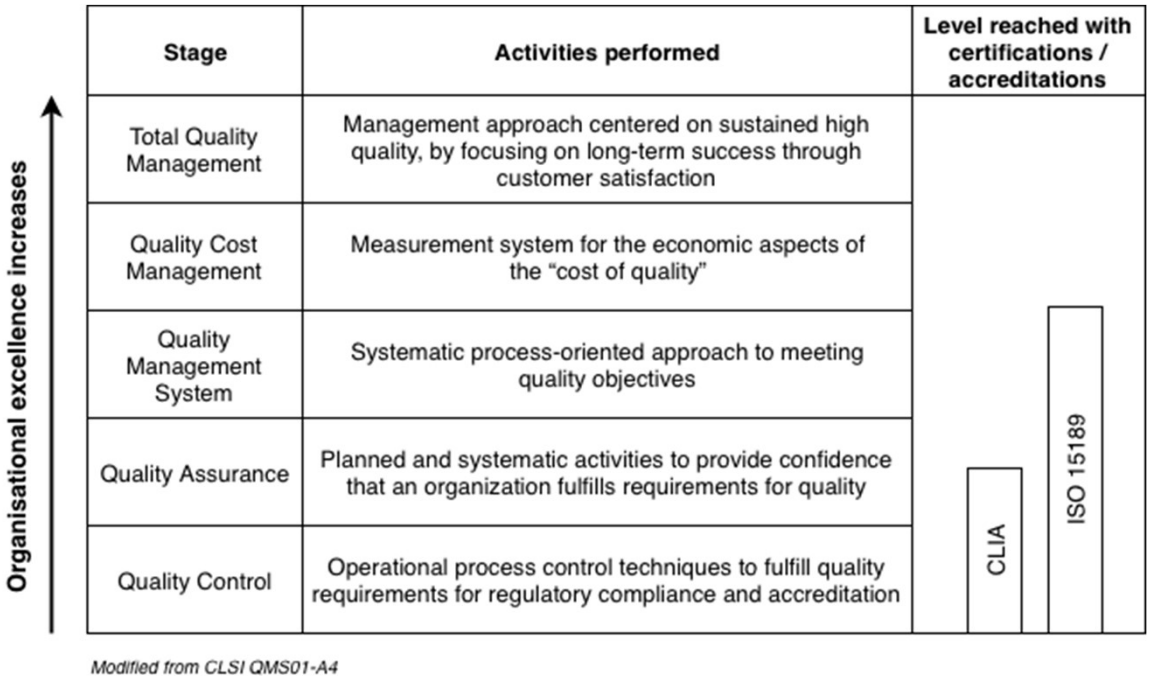
This requires not only an implemented **QMS** but also **organizational excellence**

Accreditation as a starting point for organizational excellence

- Accredited supports e.g.
  - Customer focus
  - Sustainable attainment of quality objectives
  - People and training
  - Standardization of processes
  - Reduce and eliminate deficiencies
  - Continuous “encouragement” (audits, proficiency testing…)
- Effect
  1. Customer value increases
  2. Service will become better
  3. Cost of poor quality decreases



Modified from CLSI QMS01-A4

Accreditation to support the increase of organizational excellence case ”increase in sample volumes and standardized, stable processes”

- From 2016 to 2019, our annual sample volumes have been doubled
- Meanwhile, we have been able to improve and eventually maintain failure rates below the target without sacrificing the quality of the service

Conclusion: Accreditation has helped us to shape our operations

- **customer focus, comprehensive assay and process validation, personnel training, standardization, CAPA etc…**

Accreditation and transparency to improve competitive advantage

- Fact: Accreditation is a world-wide recognition of competence
- This supports well our guiding principles - especially transparent quality
  - Detailed description of the assays incl. the strengths and limitations available to everyone
  - Comprehensive analytical validation report available to everyone
  - Result interpretation criteria (variant classification) available to everyone
  - Finally, detailed information available on accreditations and certifications

Accredited operations and competitive advantage

Summary of key benefits

- World-wide recognition of the competence of the laboratory
- In some countries accreditation is a way to meet regulatory compliance
- Periodical audits push us to standardize and continuously improve our operations

Thank you for your quality time

Olli Mikkonen
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Blueprint Genetics

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