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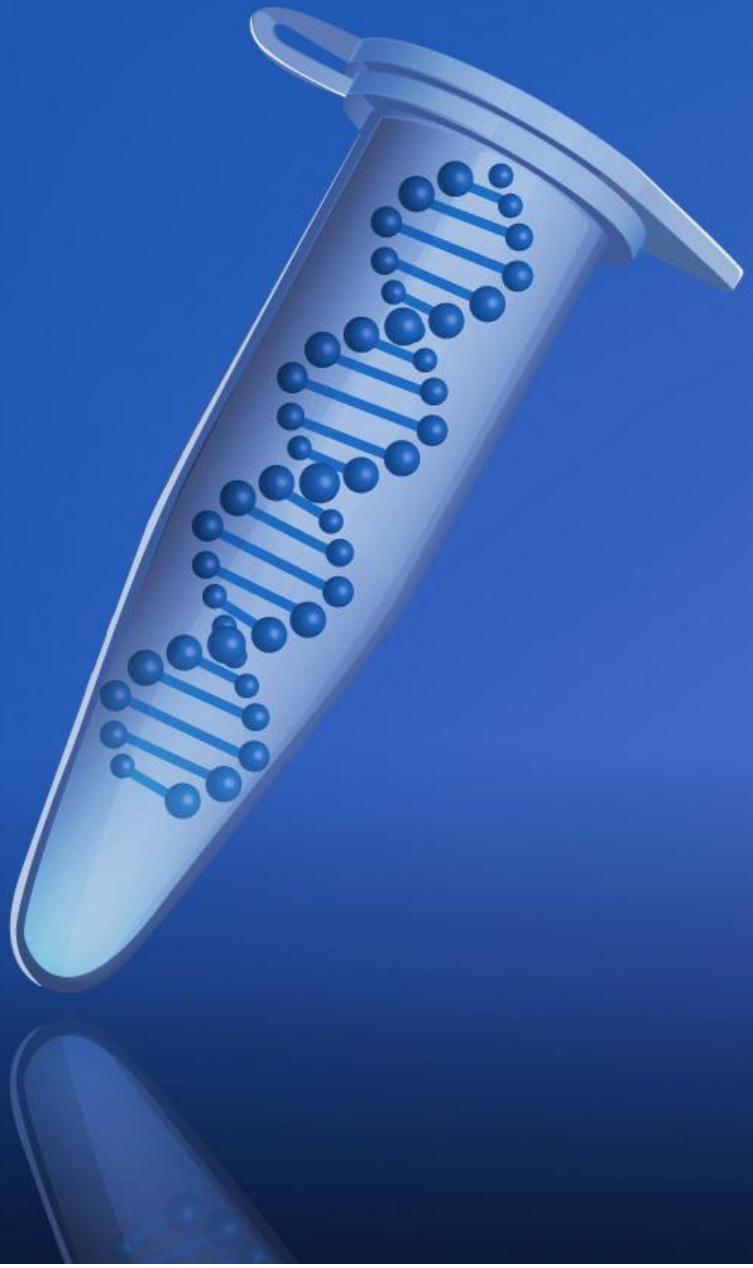

NGS

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Control

- What must be controled?
- How must it be controled?
  - Is there any possibility for controlling?
- What for must it be controlled?
  - What is the ratio between the risk to harm to health, the cost of the control and the development restraining of the controlled technology

Parts of NGS technology

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- Equipment (sequencer)
- Core consumables
- Library reagents
- Software for the NGS results interpretation

NGS technology particularities

- Equipment and core consumables are universal and are not connected with clinical data. Base reagents are integral part of equipment and depend on the manufacturer.
- Clinical data are mostly the results of library reagents and software interpreter
- Usually the interpreter is based in “cloud”. There are local solutions as well, but such interpreters demand high local computer power
- The result of sequencing present very high data volume
- The technology development is very fast and estimations of clinical significances change very quickly
  - The clinical interpretation can change for the once made research with getting the new knowledge in genetics.
- Data can comprise very big number of different analytes of different risks

Usage particularities

- Only big centres can use NGS technologies of different manufactures because of its high cost. Usually clinical labs can use only one sequencer
- NGS technology demands high qualified personal
- Low level of automation

Problems of NGS registration

- What must be controled?
  - All parts at once or departed. Open or closed technology.
- How must it be controled?
  - Closed technology
    - To be controlled with the help of “standart exom”? How “standart exom” can be created with 100% quality warranty? What diagnostic data does NGS researches present?
  - Open technology
    - Every parts are complex object. Which parameters must be controlled? If different parts are manufactured by different manufactures and every part has certificate then who is responsible for the whole technology – clinical lab?
  - How can the interpreter based in cloud be controlled?

Problems of NGS registration

- What for must it be controlled?
  - It is not possible to determine unified parameters for controlling of complex equipment of different manufactures, because they often use different technologies
  - The usage of closed NGS technology severely limits progress in the technology and usage this technology in clinical praxis because of its high cost. The reason is that clinical labs are not able to have several devices with different NGS technology

Possible solutions for NGS registration

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- Not to register sequencer and core consumables for open systems
- Possible solutions
  - A clinical institution is responsible for the whole technology. The clinical institution registers this clinical research.
  - A manufacturer of library reagents and a software interpreter is responsible for the whole technology provided that the manufacturer has a contract with a equipment manufacturer concerning providing all information about changes in equipment and base reagents. The library reagents and the interpreter are to be registered.

Possible solutions for NGS registration

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- Registration should be done only for the library reagents and the software interpreter
- Results of a clinical research should be considered as a descriptive picture without binding of analytes to nosologies (as in MRT, ultrasonography and so on).
- The interpretation are to be provided by medical specialists: medical bioinformatician and medical geneticist
  - medical bioinformatician provides the NGS results in understandable view to a medical geneticist

Possible solutions for NGS registration

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- The research results can be a comparison with the reference genome
- The known DNA sequence can be used as a control sample.
- The parameters of accuracy and reproducibility should be used instead of the parameters of sensitivity and specificity.
- The registration procedure of library reagents and software interpreter must be done simultaneously but certificates can be parted because the interpreter can be same for different libraries

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Спасибо за внимание