The Nordic Alliance for Clinical Genomics

Preparing for IVDR
Cathrine Høgseth Nordhus ([cahnor@ous-hf.no](mailto:cahnor@ous-hf.no))
NACG meeting 26. Nov 2020
The Nordic Alliance for Clinical Genomics – NACG
- an independent association open for organizational and individual members

NACG brings together leading stakeholders in clinical genomics across the Nordics.

• Mission:
  • We work together and learn from each other to lift our performance standards.
  • We aim at responsible sharing of trustworthy data for improved diagnosis and treatment, and as a resource for research.

• How we work:
  • Practical collaboration through interactive cross-disciplinary workshops and projects.
<table>
<thead>
<tr>
<th>Time (Oslo)</th>
<th>Mon 23rd Nov</th>
<th>Tue 24th Nov</th>
<th>Wed 25th Nov</th>
<th>Thu 26th Nov</th>
<th>Fri 27th Nov</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00</td>
<td><strong>Opening</strong>: Dag Undlien, NACG chair</td>
<td><strong>Keynote</strong>: Mark Caulfield, Genomics England: The Genomics in Health Implementation Forum - a mega driver project for GA4GH work based on clinical needs</td>
<td><strong>Collaborative software development</strong></td>
<td><strong>Nordic consent framework and toolkit</strong></td>
<td><strong>Preparing for IVDR</strong></td>
</tr>
<tr>
<td></td>
<td>Frederik Otzen Bagger, Head of Bioinformatics, Dept. Genomic Medicine Rigshospitalet.</td>
<td>Tony Håndstad, Bioinformatician, Department of Medical Genetics, OUS</td>
<td>Bobbie Ray-Sannerud, Programme Director Precision Medicine, DNV GL</td>
<td>Cathrine Høgseth Nordhus, Section Manager Quality, Department of Medical Genetics, OUS</td>
<td>Valtteri Wirta, Facility Director, SciLifeLab &amp; Oleg Agafonov, Researcher, DNV GL</td>
</tr>
<tr>
<td>13:00</td>
<td><strong>Emerging technologies</strong></td>
<td></td>
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<td><strong>Variant interpretation and data sharing</strong></td>
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<tr>
<td></td>
<td>Fredrik Otzen Bagger, Head of Bioinformatics, Dept. Genomic Medicine Rigshospitalet.</td>
<td></td>
<td></td>
<td></td>
<td>Dag E. Undlien, Head of Department of Medical Genetics, OUS &amp; Stephen McAdam, Digital Health Director, DNV GL</td>
</tr>
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<td>Closing</td>
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</tbody>
</table>
Connect

- NACG website
  - https://nordicclinicalgenomics.org/
- Resources
  - NACG paper
  - NACG workshop reports
  - NACG governing documents
- How to apply for membership
  - Organisations
  - Individuals
- Contact us
  - post@nordicclinicalgenomics.org
NACG - zoom meeting guidelines

• Attendees are muted by default due to the size of the groups
• Please post questions in the chat
• The workshop will be documented in a NACG report – to be published at https://nordicclinicalgenomics.org/
• Sessions are recorded to help in report production
• Please inform if anything should be kept out of the report.
NACG – for you, by you!

• Where should NACG focus next?
• Give your input through
  o Sli.do, event code: #85540
  o Post NACG-week survey
  o post@nordicclinicalgenomics.org
Preparing for IVDR
NACG November 2020

IVDR (2017 – 746)

547 days to go!
Agenda – IVDR Workshop

• Introduction
• Background – IVDR at NACG workshops
• IVDR requirements – Highlights
• IVDR status for Oslo University Hospital (Norway)
• IVDR challenges for the genetics field
• In-House Exemption/Health Institution Exemption
• Areas for collaboration
Cathrine Høgseth Nordhus (cahnor@ous-hf.no):

- Section Manager for Quality at the Department of Medical Genetics at OUS
- Master degree in Engineering Cybernetics
- 15 year Quality Management background from different fields; space, fibre optics, oil and gas and medical genetics (since 2018)
- Strong knowledge of Quality Management standards (ISO9000 series and ISO15189)
- Responsible for ensuring a smooth IVDR transition for the department of medical genetics in Oslo
- Part of the IVDR working group for genetics in Health Region South East in Norway

- Not yet expert in IVDR
## Participants – IVDR session

<table>
<thead>
<tr>
<th>Health Institutions</th>
<th>Industry</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Aalborg University Hospital</td>
<td>• Agilent</td>
<td><strong>Biobank</strong></td>
</tr>
<tr>
<td>• Aarhus University Hospital</td>
<td>• Agilent Technologies</td>
<td>• Finnish Institute for Health and Welfare (Biobank)</td>
</tr>
<tr>
<td>• Akershus University Hospital</td>
<td>• Congenica</td>
<td><strong>Government Organization</strong></td>
</tr>
<tr>
<td>• Copenhagen University Hospital (Rigshospitalet)</td>
<td>• DNV GL</td>
<td>• Danish National Genome Center</td>
</tr>
<tr>
<td>• Haukeland University Hospital</td>
<td>• Euformatics</td>
<td>• Directorate of E-health (Norway)</td>
</tr>
<tr>
<td>• Helsinki University Hospital</td>
<td>• iCellate Medical AB</td>
<td><strong>NGO</strong></td>
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<tr>
<td>• Hvidovre Hospital</td>
<td>• Illumina</td>
<td>• Colores - the Finnish Colorectal Cancer Association</td>
</tr>
<tr>
<td>• Karolinska Institutet</td>
<td>• Invitae</td>
<td>• The Norwegian Cancer Society</td>
</tr>
<tr>
<td>• Karolinska University Hospital</td>
<td>• Limbus Medical Technologies GmbH</td>
<td><strong>Research</strong></td>
</tr>
<tr>
<td>• Landspitali - University Hospital of Iceland</td>
<td>• Novartis</td>
<td>• SciLifeLab</td>
</tr>
<tr>
<td>• Lund University Hospital</td>
<td>• Oxford Nanopore Technologies</td>
<td>• Universal College of Medical Sciences, Bhairahawa, Nepal</td>
</tr>
<tr>
<td>• Norrlands University Hospital</td>
<td>• Roche Diagnostics</td>
<td>• University of Helsinki</td>
</tr>
<tr>
<td>• Oslo University Hospital</td>
<td>• SSM Health</td>
<td>• University of Luxembourg</td>
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<td>• St. Olavs Hospital, Trondheim</td>
<td>• ThermoFisher Scientific</td>
<td>• University of Luxembourg</td>
</tr>
<tr>
<td>• Turku University Hospital</td>
<td>• Twist Bioscience</td>
<td>• Universal College of Medical Sciences, Bhairahawa, Nepal</td>
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<td>• University Hospital North Norway</td>
<td>• Tyks Laboratories</td>
<td><strong>Research</strong></td>
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<td>• University Hospital of Iceland</td>
<td>• Vectorscape AB</td>
<td>• SciLifeLab</td>
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<tr>
<td>• University hospital of Umeå</td>
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<td>• Universal College of Medical Sciences, Bhairahawa, Nepal</td>
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<td>• University Hospital Örebro</td>
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<td>• University of Helsinki</td>
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<td>• Uppsala University, Uppsala University Hospital</td>
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<td>• University of Luxembourg</td>
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<tr>
<td>• Zealand University Hospital</td>
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<td>• University of Luxembourg</td>
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<td>• Örebro University Hospital</td>
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<td>• Uppsala University</td>
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## Status of IVDR preparedness per organisation type

### Preparedness for IVDR

<table>
<thead>
<tr>
<th></th>
<th>Biobank</th>
<th>Gov org</th>
<th>Healthcare</th>
<th>Industry</th>
<th>NGO</th>
<th>Research</th>
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<td>Status not given</td>
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<td>1</td>
<td>21</td>
<td>19</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>We have not started preparations yet</td>
<td>1</td>
<td>2</td>
<td>22</td>
<td>3</td>
<td>2</td>
<td>4</td>
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<tr>
<td>Work in progress</td>
<td>28</td>
<td></td>
<td></td>
<td>5</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>We feel well prepared</td>
<td>3</td>
<td></td>
<td></td>
<td>3</td>
<td></td>
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</tr>
</tbody>
</table>

The chart above shows the distribution of responses based on the status of IVDR preparedness by different types of organisations. The categories include: Status not given, We have not started preparations yet, Work in progress, and We feel well prepared. The number of respondents varies across different categories and types of organisations.
Your expectations – Sli.do Poll

• Please log onto sli.do
Goal of this NACG work shop

• All actors in the field of medical genetics will have to comply with the new European Medical Devices (MDR) and In-Vitro Diagnostics Medical Device Regulation (IVDR) by May 2020 (now 2021 due to Covid 19) and May 2022 respectively.

• The main goal of this session is:

To establish a network of professionals within NACG to collaborate on the interpretation of the IVDR and to share the burden of securing compliance with the new regulation
IVDR Requirements - Highlights
Both regulations entered into force May 26, 2017. IVDR requirements will fully apply from May 26, 2022.
No information on postponement for IVDR due to Covid-19 as of today.
Impact of the IVDR on key stakeholders

• For the public/patients
  • Safer devices and more transparency

• For manufacturers/distributors
  • Obligation to generate sufficient evidence that product is safe and performing as intended
  • Following up the safety and performance of the product when on the market (internal processes)
  • More public/media scrutiny of public product information

• For notified bodies
  • Stricter requirements concerning expertise and processes, more oversight
  • Some will go out of business -> ‘Traffic jam’ at Notified Bodies?

• For health institutions
  • Laboratories may be forced to use commercial IVDs instead of in-house developed tests
  • There will be stricter standards for the development of in-house tests
  • Regulation also applies to software (e.g. open source software that is used in bioinformatic pipelines)
# EU IVD Directive vs. IVD Regulation - What is new?

## Definition and scope
- Applies to all IVDs and their accessories
- Definition: relates to medical device definition
- New definitions and rules for: companion diagnostics (CDx), in-house tests, kits, single use IVDs and distance sales

## Key Stakeholders
- Manufacturers, Notified Bodies and Competent Authorities play key roles
- Several new bodies involved (MDCG, reference laboratories, EMA)
- Explicit roles for distributors and importers, including Responsible person for regulatory compliance

## Classification
- No longer list-based (Annex II, A or B)
- Risk based classification (A-D)

## Essential requirements
- A more detailed description of essential requirements than in Directive 98/79/EC
- Harmonised Standards and Common Specifications play a big role
- Specific rules: self-testing & NPT IVDs, CDx, genetic tests, in-house tests etc.

## Evidence
- Clarification of performance indicators (scientific validity, analytical and clinical performance)
- Explicit requirements for clinical evidence to be collected and analysed throughout the IVDs life cycle
- Performance Evaluation Reports (PER)

## Clinical studies
- Clinical performance studies required (with some exceptions)
- Some studies require prior authorisation by authorities

## CE-marking/conformity assessment
- Notified Body involved for all IVDs except class A (unless sterile)
- Involvement of EMA and reference laboratories (for some products)

## Post-market obligations
- A proactive and planned approach by the manufacturer to prove the IVDs safety and performance
- Post Market Follow-Up Plan
- Continuous updates on the performance will be required

## Transparency & traceability
- EUDAMED database accessible to several stakeholders including the public
- Transparency of data from clinical performance studies
- Unique Device Identifier (UDI) to ensure traceability in the supply chain

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From presentation by Roche June 2019
New Classification System – Stricter Approval Requirements

Medical Devices

- **Class III**
  - Examples: Pacemakers, heart valves, implanted cerebral stimulators

- **Class IIb**
  - Examples: Condoms, lung ventilators, bone fixation plates

- **Class IIa**
  - Examples: Dental fillings, surgical clips, transvaginal tissues

- **Class I**
  - Examples: Wheelchairs, stethoscopes, spectacles

In Vitro Diagnostic Medical Devices

- **Class D**
  - Examples: Hepatitis B blood donor screening, HPA blood diagnostic test; ABO blood grouping

- **Class C**
  - Examples: Blood glucose self-testing, PSA screening, HLA typing

- **Class B**
  - Examples: Pregnancy self-testing, urine test strips, cholesterol self-testing

- **Class A**
  - Examples: Clinical chemistry analyzers, specimen stabilization, prepared selective culture media

Genetic Tests

Oslo University Hospital
Classification of genetics tests under IVDR

- Classification of genetic tests is simple:
  
  All genetic test IVDs are class C devices

- All class C IVDs will require the involvement of Notified Bodies for their placement on the market

- Most genetic tests in use in Norway today typically fit into what is called the Health Institution Exemption/In House Exemption
Status for Norway
+ IVDR at NACG and BIGMED
**Norway – Key Information – IVDR and Genetics**

<table>
<thead>
<tr>
<th>Competent Authority</th>
<th>Notified Bodies</th>
<th>Medical Genetics Departments</th>
<th>Genetic Tests Available</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Statens legemiddelverk</strong></td>
<td>None approved for IVDR in Norway yet, but DNV GL is pursuing approval</td>
<td><strong>Oslo University Hospital</strong> (Oslo)</td>
<td><strong>Tests at Oslo University Hospital</strong></td>
</tr>
<tr>
<td>Norwegian Medicines Agency</td>
<td></td>
<td><strong>Sykehuset Telemark</strong> (Skien)</td>
<td><strong>Tests at Sykehuset Telemark</strong></td>
</tr>
<tr>
<td></td>
<td><em>Up-to-date information about notified bodies is available through NANDO</em></td>
<td><strong>St Olavs Hospital</strong> (Trondheim)</td>
<td><strong>Tests at St Olavs Hospital</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Haukeland Sykehus</strong> (Bergen)</td>
<td><strong>Tests at Haukeland Sykehus</strong></td>
</tr>
<tr>
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<td></td>
<td><strong>University Hospital Northern Norway</strong> (Tromsø)</td>
<td><strong>Tests at University Hospital Northern Norway</strong></td>
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</tbody>
</table>

www.Genetikkportalen.no
IVDR Project at Oslo University Hospital (OUS) and Health Region South East

**IVDR project group**
PM: Espen Kibsgård  
UXKISP@ous-hf.no

- **Genetics Work Group**  
  GL: Mohsen Shahidi  
  moshad@ous-hf.no
- **Clinical Chemistry & Pharmacology**  
  GL: Rolf Anton Klaasen
- **Microbiology WG**  
  GL: Espen Kibsgård

**Challenges for medical genetics field:**
- Highly complex methods which includes the use of algorithms as part of the examination of blood or tissue to obtain in-vitro information concerning diagnosis of or predisposition to a medical condition or a disease

**Hospitals/Labs involved in the HSE Project group/work groups in 2020:**
- Oslo University Hospital
- Akershus University Hospital
- Sykehuset Østfold
- Sykehuset Telemark
- Sørlandet Sykehus
- Innlandet Sykehus

**Health region South East set up an IVDR project group in 2019.**
**Separate work group for genetics was established in the project early 2020.**
**The project is now working to establish closer contact with the rest of Norway’s hospitals - Kick off meeting held in October 2020.**
**This presentation is partly based on the work done in the project group**
## Project Group Health Region South East - Status

### Communication with competent authority

- No guidelines for the interpretation of the new regulation have been provided in Norway
- The various stakeholders have provided input during the consultation process for the new regulation
- Request for clarification has been sent to Legemiddelverket from the IVDR project team in HSØ.

### Mapping and classification of IVDs

- Mapping of IVDs in use and classification* is underway in all work groups
- Market surveillance has started in some work groups

*All genetics tests are class C IVDs

### Procedures for IVDR compliance

- Draft procedure for Market Surveillance, incl. templates
- Draft procedure for self declaration of inhouse IVDs, including templates
Background – IVDR at NACG meetings

Copenhagen, November 2018
Courtney Nadeau, DNV GL, introduced the IVDR which replaces previous IVD directive 98/79/EC and takes primacy over national law.

Oslo, November 2019
Alexey Shiryaev and Nick Baker, both from DNV GL Presafe AS, provided an overview of the MDR and IVDR, discussed applicability and requirements for transition.

Webinar, November 2020
Cathrine Nordhus, OUS, presents status of work in Norway and with a goal to establish working groups that will collaborate across the Nordic region.
IVDR related white papers available through Big Med Project
Main Challenges
Medical Genetics
Risks and Challenges for the Genetics Field

General concerns

• European rules and regulations for in-vitro-diagnostic manufacturers are becoming increasingly complex and stringent
  • 20% of IVDs\(^1\) required CE marking under IVDD (Directive 98/79/EC)
  • 80% of IVDs\(^1\) will require CE marking under IVDR (Regulation (EU) 2017/746)

• The IVDR is very comprehensive and it will require significant effort from the various health institutions and manufacturers to interpret and ensure compliance to the requirements in the regulation

• There is a lack of guidance from competent authorities on how to interpret the different requirements.

• There are concerns about increased cost as a result of CE marking process that will impact hospital budgets / diagnostic test repertoire.

• There might be a need to move towards CE marking of some laboratory developed tests

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1. Estimated that there were \(~40000\) IVDs on the market in Europe in 2019
Complexity of genetic tests

- The main challenge for the application of IVDR is the complexity of genetic tests:
  - The wet lab uses many different types of chemicals, consumables and equipment to prepare the samples for the sequencing step
    - So far a large part of these are marked «For Research Only» or “Research Use”
    - Existing equipment in the Health Institution is not CE-marked
  - The bioinformatic pipelines that analyse the consists of many different steps
    - The pipeline consists of a combination of scripts that are either «open source» or developed «In-house»
Risks and Challenges for the Genetics Field

Availability of commercial CE marked kits/reagents and equipment

• The Medical genetics field is experiencing rapid development and it is expected that it will be a challenge to find commercially available CE marked IVDs that can meet the various patient groups’ need for state-of-the-art diagnostics

• The need for CE marking and notified body involvement for placement of IVDs on the market could lead to delayed access or lack of access to new technology in the genetics field.

• The lack of notified bodies for the IVDR (currently only 4 in Europe) and the massive increase in IVDs that need notified body involvement to be CE marked (from 20% today to 80% after 2022) can impact when CE marked IVDs become available

• Equipment in use in health institutions today are not CE-marked – will IVDR impact investment needs?

• How will the IVDR impact availability of IVDs tailored for the rare and ultra rare disease field? Will commercial alternatives be developed?
Risks and Challenges for the Genetics Field

Health Institution Exemption

• The Health Institution Exemption or In-House Exemption will require all health institutions to review all laboratory develop tests to ensure that they meet the requirements of the Safety and Performance Requirements in Annex 1 of the IVDR:

  • This will require resources to map existing documentation to the declaration forms
  • This will require resources to justify using laboratory developed tests over CE marked commercial alternatives
  • This may require additional validation and verification work
  • This may require additional work to meet the performance evaluation requirements
  • There may be a need to review the appropriateness of the quality management system of the health institution
  • There may be a need to develop best practices for requirements that will be applicable for health institutions under the new regulation.
Risks and Challenges for the Genetics Field

ICT Tools

The department of medical genetics at OUS develops bioinformatics pipelines and variant interpretation tools and the department has significant competency within the field. This gives us great flexibility to implement state of the art methodology in diagnostics and gives us good control of data sources. The same ICT tool is used for various analyses.

*IVDR Recital 17:*

> It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of an in vitro diagnostic medical device, qualifies as an in vitro diagnostic medical device, while software for general purposes, even when used in a healthcare setting, or software intended for well-being purposes is not an in vitro diagnostic medical device. The qualification of software, either as a device or an accessory, is independent of the software’s location or the type of interconnection between the software and a device.

The meaning of the term “software for general purposes” has been a topic for discussion in Oslo. Will our variant interpretation tool, Ella, be considered an IVD even if the tool is used for multiple IVDs?
Risks and Challenges for the Genetics Field

Algorithms and IVDR

Algorithms play a big part in genetic analysis and this poses challenges both for regulators and developers.

The publications Algorithms as Medical Devices and Regulating Algorithms in Healthcare by the PHG foundation looks at the challenges posed by algorithms as part of medical devices:

- The rapid changes resulting from machine learning models that continuously retrain
- Interpretability and transparency of algorithms (in particular Black Box algorithms and Dynamic Machine Learning Devices)
- The challenge of validating algorithms to ensure that they fulfil their intended purpose
- Lack of harmonized standards to assist with compliance

These publications also compare how algorithms are regulated under IVDR and under FDA. Another relevant publication from PHG is Black Box Medicine and Transparency.
Risks and Challenges – Sli.do Poll

• Please log onto sli.do using event code #80417

Which of the challenges discussed in this presentation do you see as the biggest challenges for your organisation?

- Interpretation of the regulation
- Complexity of the genetic test IVDs
- Lack of resources within your organization dedicated to IVDR work
- Lack of guidance from competent authorities
- Availability of CE marked IVDs on the market
- Lack of notified bodies
- Use of ICT tools
- Understanding how to apply IVDR to algorithms

Are there any other risks or challenges that you see, that have not been mentioned in my slides?
Preparing for IVDR

5 minute break
In House Exemption / Health Institution Exemption
Health Institution Exemption

The IVDR allows health institutions under certain conditions to manufacture modify and use laboratory developed tests:

A minimum requirement is that all inhouse tests must meet the safety and performance requirements described in Annex 1 of the IVDR. The other conditions are:

a) Internal use only - One legal entity
b) Appropriate quality management systems (ISO13485)
c) Laboratory must be compliant with ISO15189
d) Patient group's specific needs cannot be met by commercial alternative
e) Health institution must provide information upon request on the use of LDTs to its competent authority
f) Health institution must make declaration (stating safety and performance requirements compliance) publicly available
g) Specific to Class D IVDs (but can be required by national competent authority for lower risk class IVDs)
h) Specific to Class D IVDs (but can be required by national competent authority for lower risk class IVDs)
i) The health institution must review experience gained from clinical use of the devices and take necessary corrective action
**In house IVD - Documentation requirements**

**Declaration**
- Declares that all requirements relevant for laboratory developed tests are met.
- Provides an overview of all documentation

**Market Surveillance**
- Health institutions must document that no commercial alternatives are able to meet patients' needs

**Method Documentation**
- Detailed description on IVD test method for laboratory staff including:
  - Detailed Procedures and work instructions
  - Information on storage, shelf life, procedures for disposal of equipment/reagents
  - This is equivalent to the IVDs «instructions for use»

**IVD Manufacturing method**
- Documents how a particular IVD is set up (process flow charts for genetics?)

**Validation Report**
- Documents that the IVD works as intended

**New requirements in IVDR**

**Typically already documented in Quality Management System**
Declaration Form – Part A1: Legal Entity Information

- Describes who is considered as manufacturer of inhouse IVDs
  (IVDR article 5.5 f) (i))

- The IVD can only be used within this particular legal entity
  (IVDR article 5.5 a)
• Declares that the IVD is used under the inhouse exemption
• Declares that relevant Safety and Performance requirements in annex 1 are met
• Declaires that the IVD is manufactured under an appropriate QMS
Declaration Form – Part B: What the declaration covers

List of IVDs that the declaration covers (one declaration can be more than one IVD)

**Column description**

*Roman number:* Links the IVD to relevant section in Part C of the declaration  
*IVD-description:* Name of IVD  
*Coding system:* International coding system (if relevant)  
*Referanse code:* Relevant code from coding system

### Del B - IVD-utstyr

<table>
<thead>
<tr>
<th>IVD-utstyr</th>
<th>Kodesystem</th>
<th>Referansekode</th>
</tr>
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<tbody>
<tr>
<td>Anti-TG2</td>
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<td>Inflaksimab</td>
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</tr>
<tr>
<td>Steroider B</td>
<td>Internt</td>
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</tr>
</tbody>
</table>
Declaration Form – Part C

- One Part C per IVD listed in Part B of the declaration form linked with Roman number + IVD name

- List documents that confirms compliance to safety and performance requirements in Annex (to be included as attachments)

- Description of intended purpose

- Documents needs of patient group cannot be met by commercially available and CE marked IVD

- Shows IVD classification and reason for classification
The project team in Norway has also developed procedures for how to perform market surveillance and templates for how to document market surveillance activities.

Market surveys will have to be performed on a regular basis to cover developments in the market.

Collaboration between health institutions and also between industry and health institutions will help to reduce the burden of ensuring compliance.
Areas for Collaboration / Moving Forward
Areas for collaboration

**Health Institutions**

- Interpretation of IVDR requirements for Genetics Tests – in particular for inhouse IVDs
- Building/sharing arguments for use of in-house IVDs
- Establish templates for self-declaration for inhouse invitro diagnostic devices
- Establishing best practices for validation of in-house methods – in particular for the bioinformatic part of genetic tests
- Collaborating on market surveillance activities
- Sharing experiences from accreditation process to laboratories in process of being accredited to ISO15189

**Health Institutions and Industry**

- Establishing meeting points for presenting new CE marked IVDs on a regular basis
- Discussions on need for new CE-marked IVDs
- Discussion on how to ensure a smooth market surveillance process
Areas for Collaboration - Slido

• Please log onto sli.do using event code #80417
Resources – overview

Internal resources
Presentations given by Espen Kibsgård and Rolf Anton Klaasen at Norwegian information meeting in October

IVDR:

Various resources on the internet:
• https://www.phgfoundation.org/briefing/what-is-the-ivdr
• https://d2evkimvhatqav.cloudfront.net/documents/md_wp_ivdr.pdf
• https://blog.limbus-medtec.com/the-ivdr-affects-how-genetic-testing-laboratories-can-operate-all-over-europe-c39749e8ef07

Nando – Database with list of Notified Bodies:
• https://ec.europa.eu/growth/tools-databases/nando/index.cfm
# Notified Bodies per 20/11/2020

<table>
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<tr>
<th>Body type</th>
<th>Name</th>
<th>Country</th>
<th>MDR</th>
<th>IVDR</th>
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<tr>
<td>NB 2265</td>
<td>3EC International a.s.</td>
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<tr>
<td>NB 0086</td>
<td>BSI Assurance UK Ltd</td>
<td>United Kingdom</td>
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<td>NB 2797</td>
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<td>NB 2409</td>
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<td>NB 0124</td>
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<td>NB 2460</td>
<td>DNV GL Presafe AS</td>
<td>Norway</td>
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<td>NB 0297</td>
<td>DQS Medizinprodukte GmbH</td>
<td>Germany</td>
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<td>NB 0459</td>
<td>GMED</td>
<td>France</td>
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<td>IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.</td>
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<td>NB 2862</td>
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<td>MDG MEDICAL DEVICE CERTIFICATION GMBH</td>
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