The Nordic Alliance for Clinical Genomics

Preparing for IVDR

Cathrine Høgseth Nordhus (cahnor@ous-hf.no)

NACG meeting 26. Nov 2020

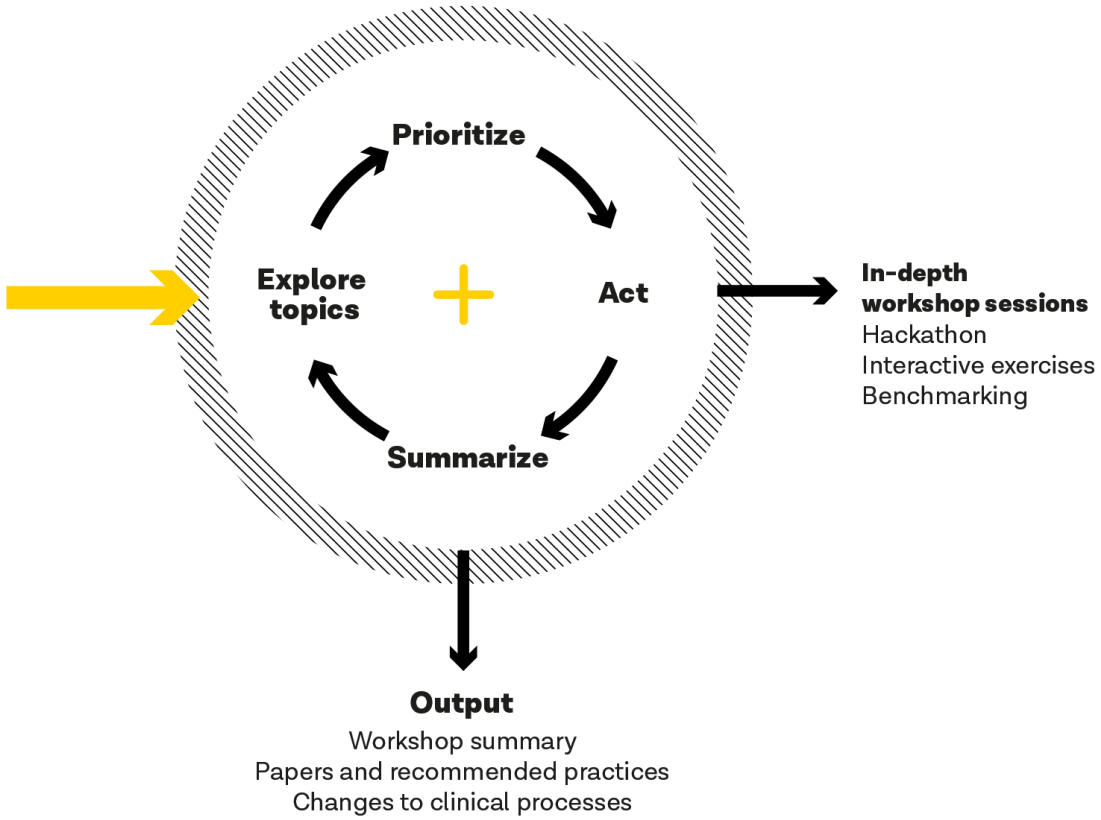
Nordic Alliance
for Clinical Genomics

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.



NACG week agenda

If you would like to join any additional sessions, please contact post@nordicclinicalgenomics.org

Time (Oslo)	Mon 23rd Nov	Tue 24th Nov	Wed 25th Nov	Thu 26th Nov	Fri 27th Nov
12:00	**Opening**: Dag Undlien, NACG chair **Keynote**: Mark Caulfield, Genomics England: The Genomics in Health Implementation Forum - a mega driver project for GA4GH work based on clinical needs	**Collaborative software development** Tony Håndstad, Bioinformatician, Department of Medical Genetics, OUS	**Nordic consent framework and toolkit** Bobbie Ray-Sannerud, Programme Director Precision Medicine, DNV GL	**Preparing for IVDR** Cathrine Høgseth Nordhus, Section Manager Quality, Department of Medical Genetics, OUS	**Cancer panel benchmarking** Valtteri Wirta, Facility Director, SciLifeLab & Oleg Agafonov, Researcher, DNV GL
13:00	**Emerging technologies** Frederik Otzen Bagger, Head of Bioinformatics, Dept. Genomic Medicine Rigshospitalet.				**Variant interpretation and data sharing** Dag E. Undlien, Head of Department of Medical Genetics, OUS & Stephen McAdam, Digital Health Director, DNV GL Closing

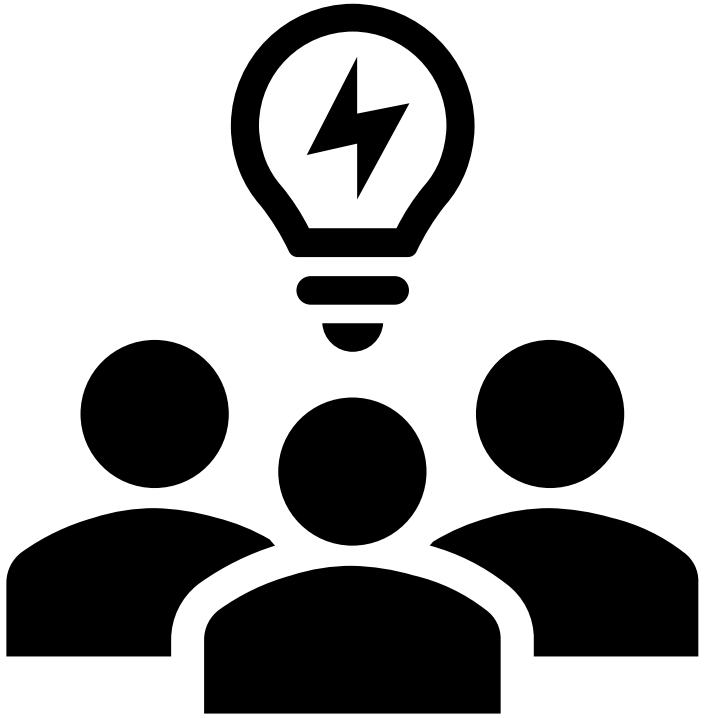
Connect

- 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 du 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!

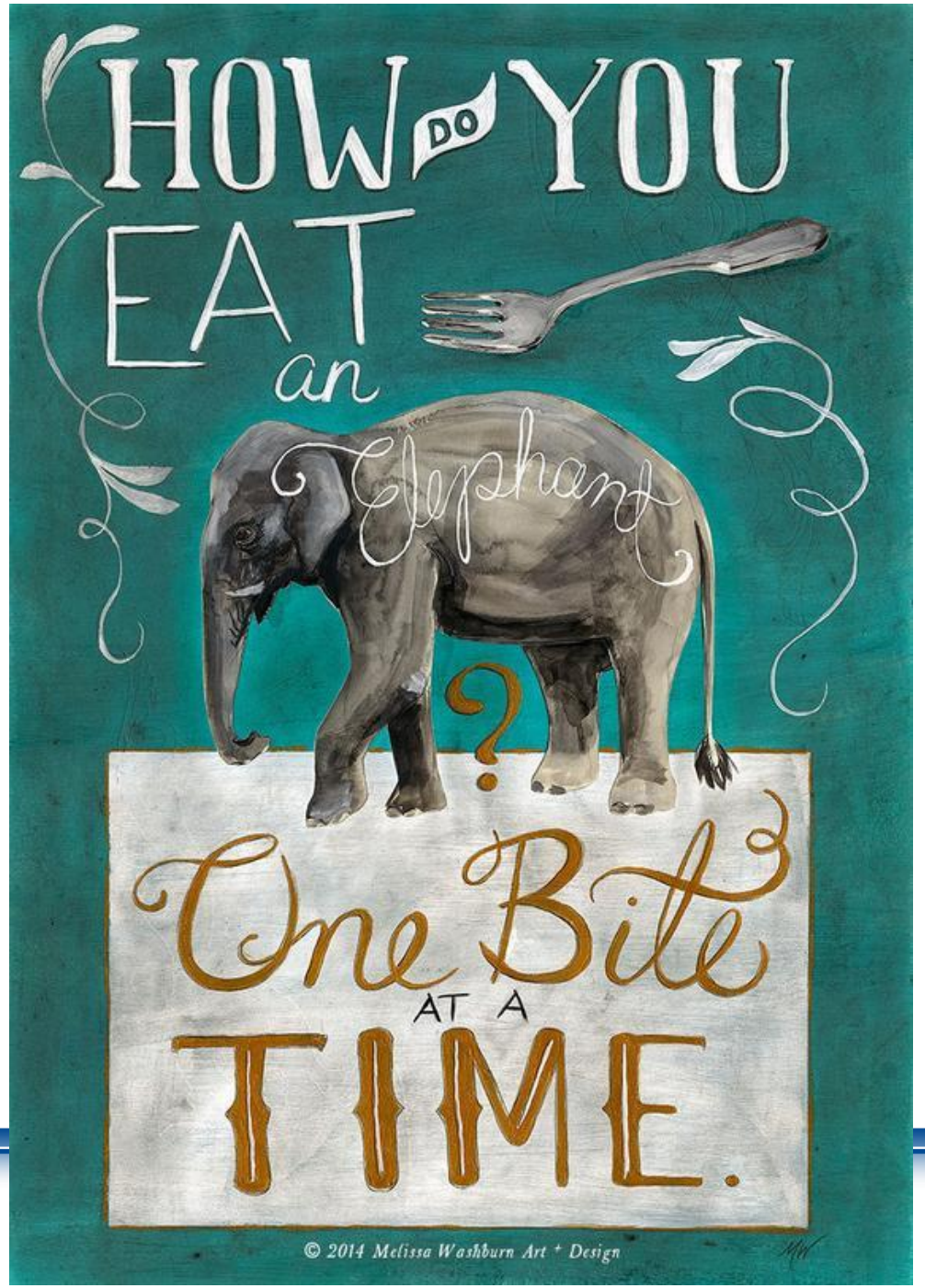


- Where should NACG focus next?
- Give your input through
  - **Sli.do, event code: #85540**
  - Post NACG-week survey
  - post@nordicclinicalgenomics.org

Preparing for IVDR

NACG November 2020

547 days to go!



Oslo University Hospital

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

Introduction

- 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

Health Institutions

- Aalborg University Hospital
- Aarhus University Hospital
- Akershus University Hospital
- Copenhagen University Hospital (Rigshospitalet)
- Haukeland University Hospital
- Helsinki University Hospital
- Hvidovre Hospital
- Karolinska Institutet
- Karolinska University Hospital
- Landspitali - University Hospital of Iceland
- Lund University Hospital
- Norrlands University Hospital
- Oslo University Hospital
- St. Olavs Hospital, Trondheim
- Turku University Hospital
- University Hospital North Norway
- University Hospital of Iceland
- University hospital of Umeå
- University Hospital Örebro
- Uppsala University, Uppsala University Hospital
- Zealand University Hospital
- Örebro University Hospital

Industry

- Agilent
- Agilent Technologies
- Congenica
- DNV GL
- Euformatics
- iCellate Medical AB
- Illumina
- Invitae
- Limbus Medical Technologies GmbH
- Novartis
- Oxford Nanopore Technologies
- Roche Diagnostics
- SSM Health
- ThermoFisher Scientific
- Twist Bioscience
- Tyks Laboratories
- Vectorscape AB

Other

Biobank

- Finnish Institute for Health and Welfare (Biobank)

Government Organization

- Danish National Genome Center
- Directorate of E-health (Norway)

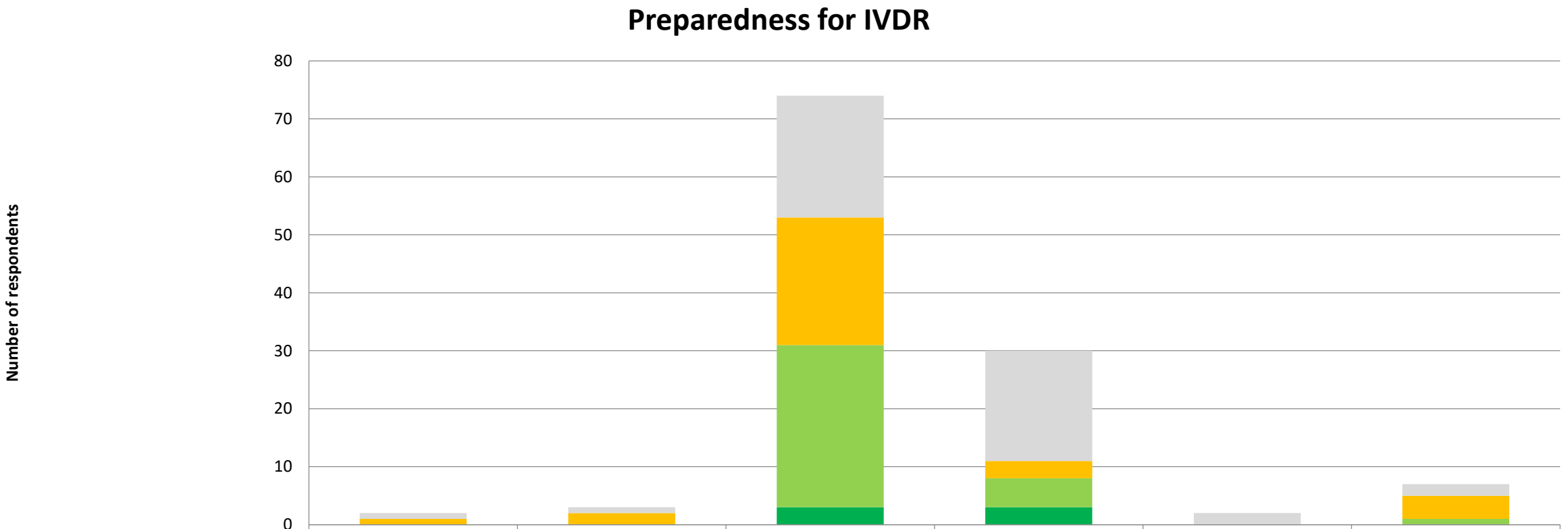
NGO

- Colores - the Finnish Colorectal Cancer Association
- The Norwegian Cancer Society

Research

- SciLifeLab
- Universal College of Medical Sciences, Bhairahawa, Nepal
- University of Helsinki
- University of Luxembourg
- Uppsala University

Status of IVDR preparedness per organisation type



	Biobank	Gov org	Healthcare	Industry	NGO	Research
Status not given	1	1	21	19	2	2
We have not started preparations yet	1	2	22	3		4
Work in progress			28	5		1
We feel well prepared			3	3		

Your expectations – Sli.do Poll

- Please log onto sli.do

Goal of this NACG work shop

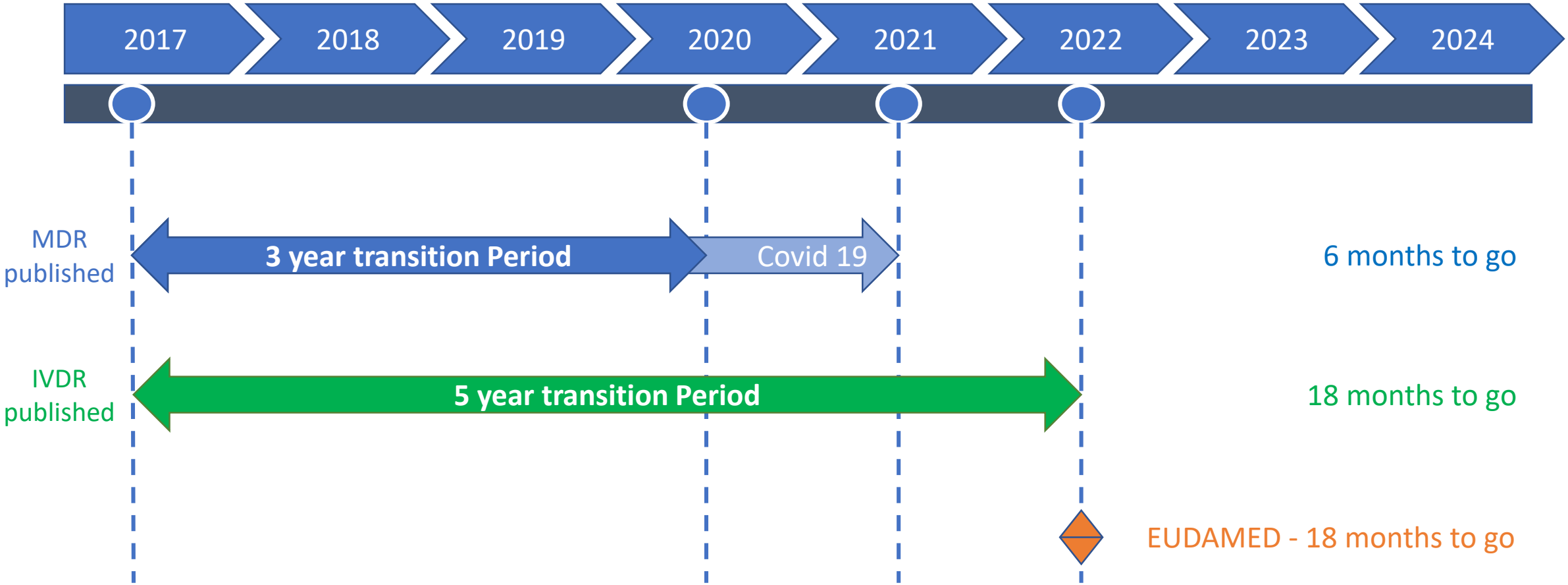
- All actors in the field of medical genetics will have to comply with the new European Medical Devices (MDR) and In-Vitro Diagnostics Medical Device Regulation (IVDR) by May 2020 (now 2021 due to Covid 19) and May 2022 respectively.

- 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

Timeline – MDR and IVDR



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

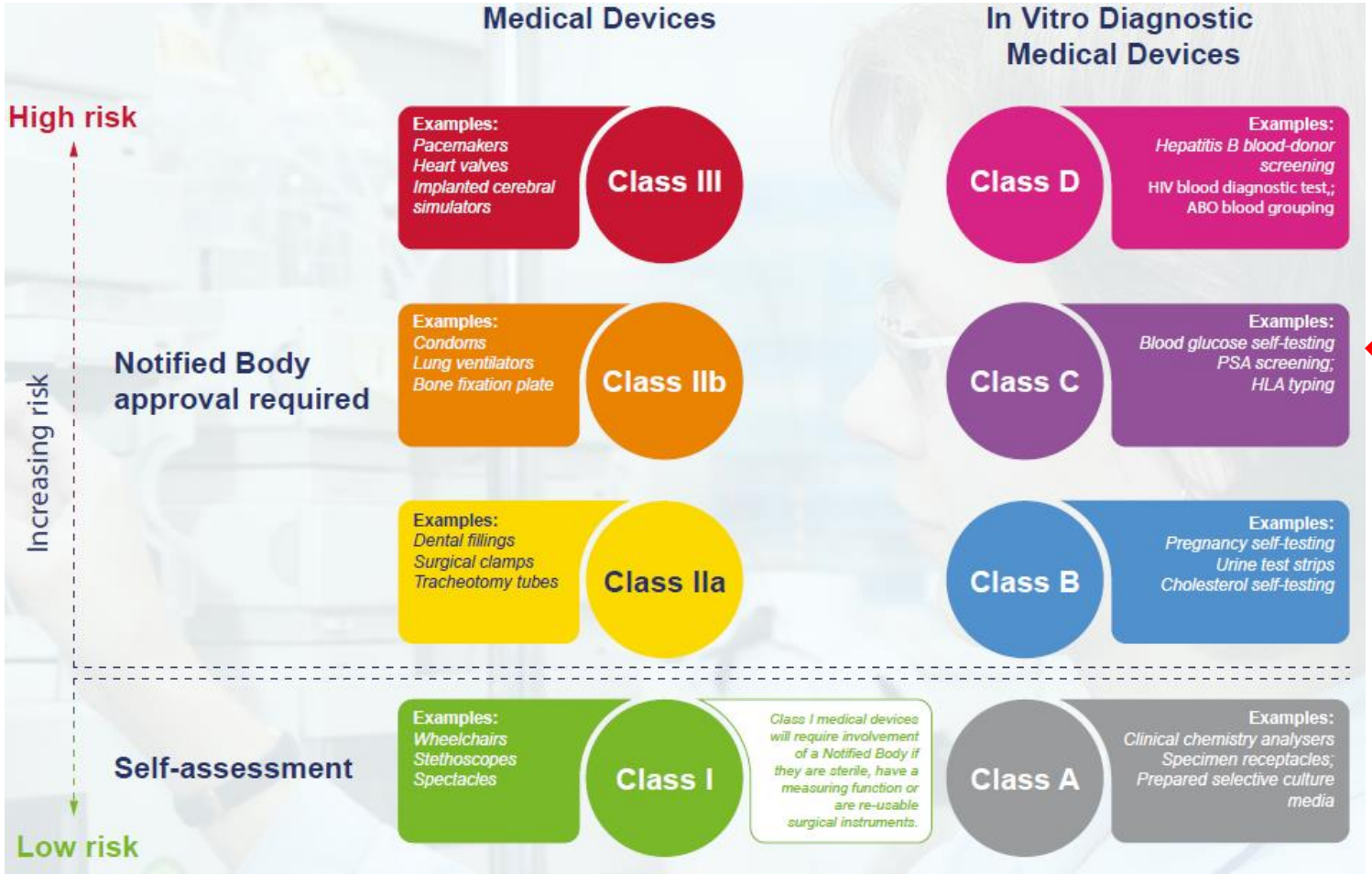
- A proactive and planned approach by the manufacturer to prove the IVDs safety and performance
- Post Market Follow-Up Plan
- Continuous updates on the performance will be required

Transparency & traceability

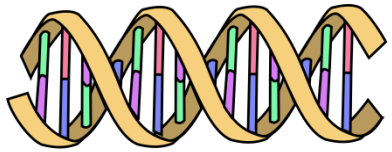
- EUDAMED database accessible to several stakeholders including the public
- Transparency of data from clinical performance studies
- Unique Device Identifier (UDI) to ensure traceability in the supply chain

From presentation by Roche June 2019

New Classification System – Stricter Approval Requirements



Genetic Tests



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 the Health Institution Exemption/In House Exemption

Status for Norway

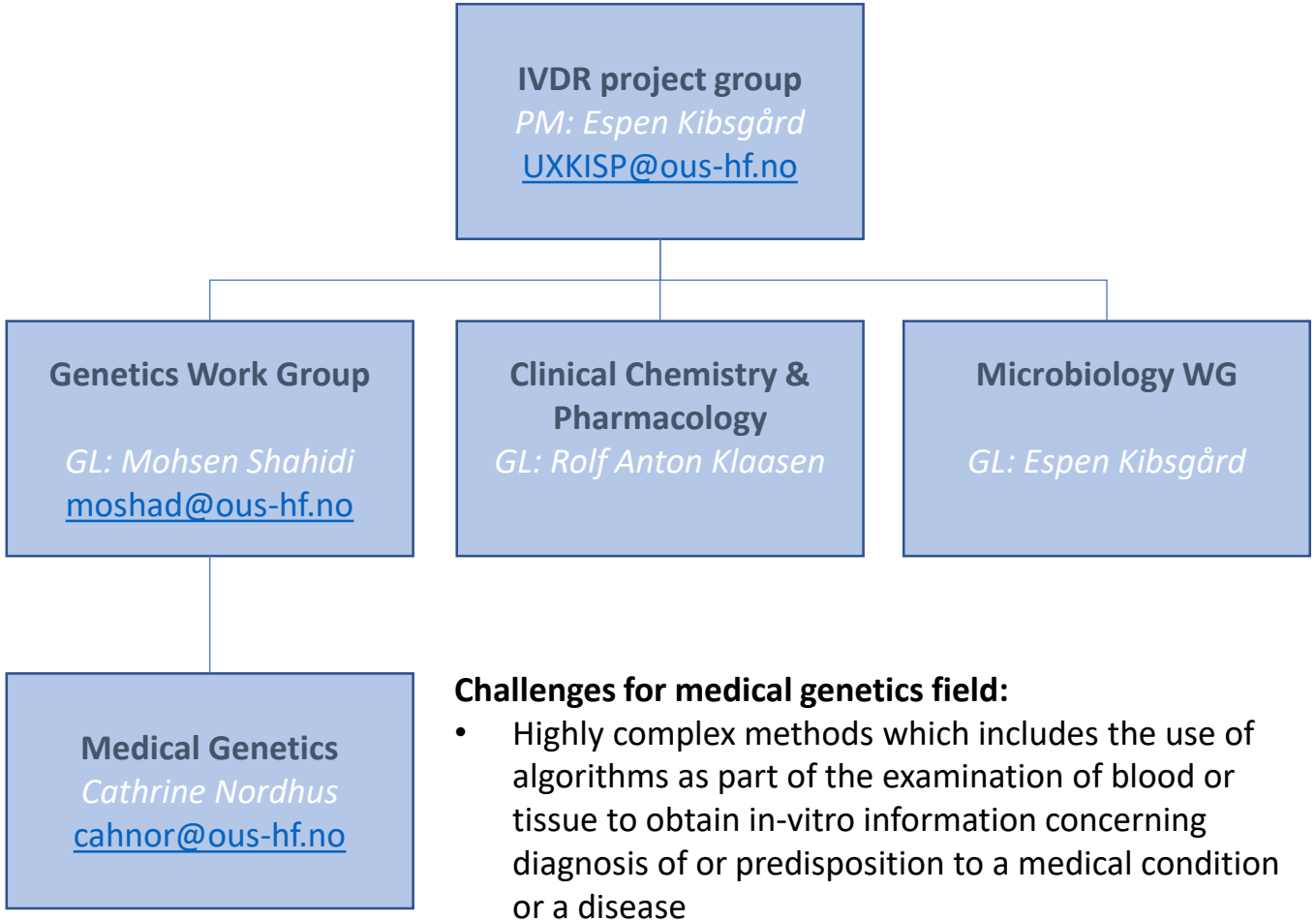
+ IVDR at NACG and BIGMED

Norway – Key Information – IVDR and Genetics

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

www.Genetikkportalen.no

IVDR Project at Oslo University Hospital(OUS) and Health Region South East



- Health region South East set up an IVDR project group inn 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

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

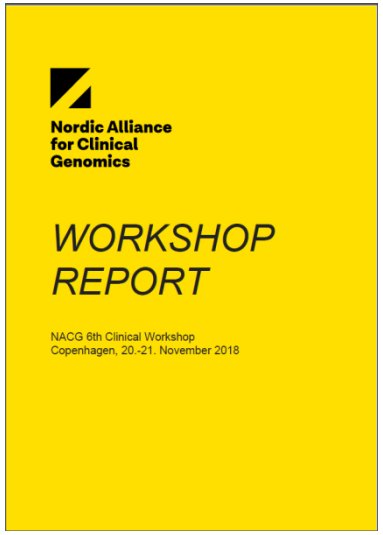
Project Group Health Region South East - Status

Communication with competent authority	Mapping and classification of IVDs	Procedures for IVDR compliance
• 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 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**	• Draft procedure for Market Surveillance, incl. templates • Draft procedure for self declaration of inhouse IVDs, including templates

Background – IVDR at NACG meetings

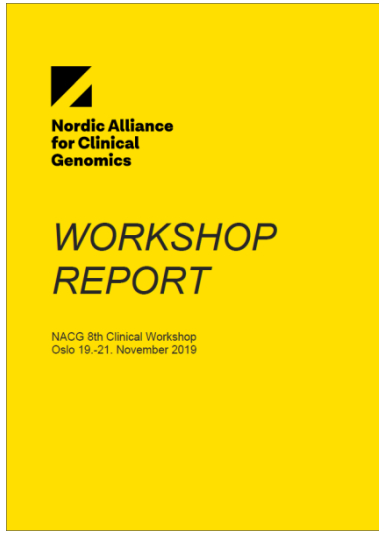
Copenhagen, November 2018

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



Oslo, November 2019

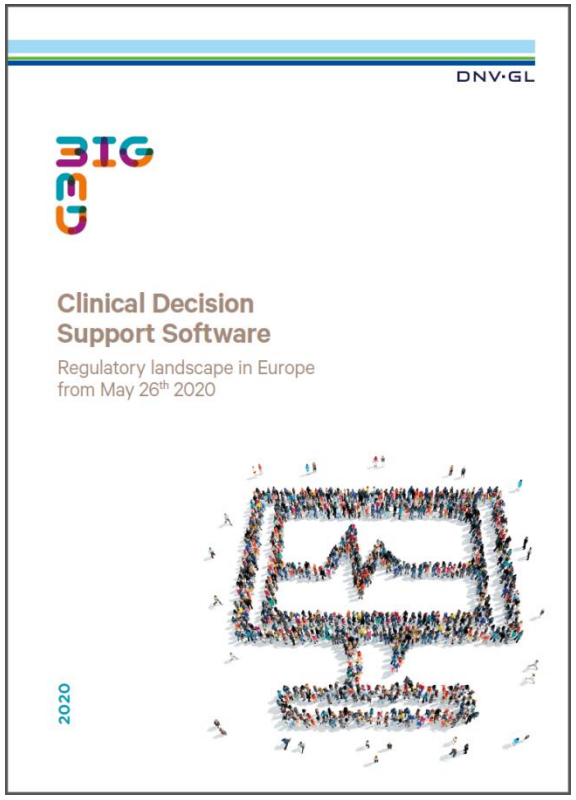
Alexey Shiryaev and Nick Baker, both from DNV GL Presafe AS, provided an overview of the MDR and IVDR, discussed applicability and requirements for transition.



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-diagnostics 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

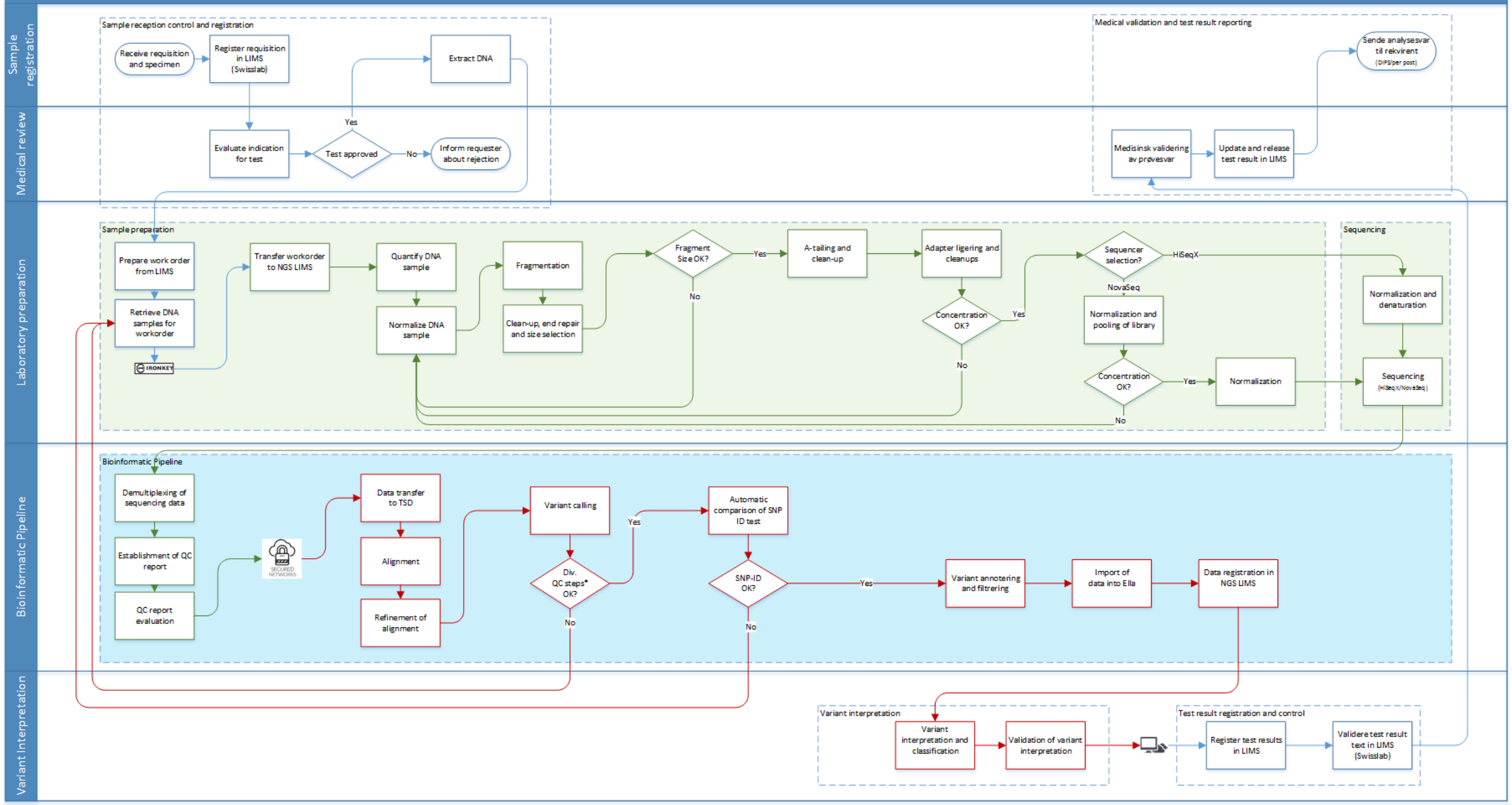
1. Estimated that there were ~40000 IVDs on the market in Europe in 2019

Risks and Challenges for the Genetics Field

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»

HTS Genom (Singel GATK pipeline)



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

Nordic Alliance
for Clinical Genomics

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) Spesific to Class D IVDs (but can be required by national competent authority for lower risk class IVDs)
h) Spesific 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

New requirements in IVDR

Declaration

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

Market Surveillance

- Health institutions must document that no commercial alternatives are able to meet patients needs

Typically already documented in Quality Managment System

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

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)

A.1 Produsentinformasjon

Navn:	Oslo universitetssykehus
Organisasjonsnummer.:	993 467 049
Adresse:	Ullernchausseen 70 0379 Oslo
Kontaktperson:	Kari Nordman
Stilling:	Laboratorieleder
Avdeling:	Sentrallaboratoriet
Telefon:	99 88 77 66
Epost:	Kari.nordmann@ous-hf.no

Declaration Form – Part A1: Declaration

- 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

A.2 Deklarasjon

IVD-utstyr angitt i del B fremstilles og anvendes i denne helseinstitusjonen i henhold til kravene i EU Forordning 2017/746 Artikkel 5 nr. 5 og oppfyller de generelle kravene i Vedlegg I. Alt IVD-utstyr fremstilles og anvendes som beskrevet i organisasjonens interne kvalitetssystem. Krav i Vedlegg I som ikke er fullt ut oppfylt og en begrunnelse for dette er angitt i del C. Dokumentasjon kan utleveres på forespørsel til autorisert myndighet	Signatur på vegne av organisasjonen Kari Nordmann …… Navn: Kari Nordmann Dato: 22/05/2022

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 i 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

Deklarasjonen i Del A gjelder for følgende IVD-utstyr:

	IVD-utstyr	Kodesystem	Referansekode
I	Anti-TG2	GMDN	55225
II	Infliksimab	Internt	A1225
III	Soppmidler A	Internt	D5687
IV	Steroider B	Internt	12345

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

Del C- Utstyr I – anti-TG2

Referansekode	GMDN 55225
Referanse til teknisk dokumentasjon	**A123 Metodedokument** **A456 Fremstillingsprosedyre** **A789 Valideringsrapport**
Tiltenkt bruk	Bestemmelse av antistoffer mot transglutaminase 2 i forbindelse med utredning av cøliaki
Mangel på tilsvarende IVD-utstyr på markedet.	Utstyr tilsvarende IVD-utstyr anført over er ikke funnet på markedet. Dokumentasjon på manglende tilsvarende IVD-utstyr plassert på markedet foreligger i Dok id A741

Risiko-klassifisering (A-D)	B
Begrunnelse	Det angitte IVD-utstyret er vurdert til å være i risikoklasse angitt over etter Regel 6

Market Surveillance

- 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

Health institutions: Which of the proposed collaboration possibilities would you consider joining

- 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

Industry: Which of the proposed collaboration proposals would you consider joining

- 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

Are there any other collaboration initiatives that you would like to see. Please indicate which category (A= Health Institution 2 Health Institution, B = Health institution 2 Industry)

Resources – overview

Internal resources

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

IVDR:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0746

Various resources on the internet:

- https://www.phgfoundation.org/briefing/what-is-the-ivdr
- https://www.phgfoundation.org/documents/algorithms-ivdr-gdpr-workshop-report.pdf
- https://www.phgfoundation.org/documents/algorithms-as-medical-devices.pdf
- https://d2evkimvhatqav.cloudfront.net/documents/md_wp_ivdr.pdf
- https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies
- 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

Body type	Name	Country	MDR	IVDR
NB 2265	3EC International a.s.	Slovakia	X	
NB 0086	BSI Assurance UK Ltd	United Kingdom	X	X
NB 2797	BSI Group The Netherlands B.V.	Netherlands	X	X
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary	X	
NB 1912	DARE!! Services B.V.	Netherlands	X	
NB 0344	DEKRA Certification B.V.	Netherlands	X	
NB 0124	DEKRA Certification GmbH	Germany	X	X
NB 2460	DNV GL Presafe AS	Norway	X	
NB 0297	DQS Medizinprodukte GmbH	Germany	X	
NB 0459	GMED	France	X	
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy	X	
NB 2862	Intertek Medical Notified Body AB	Sweden	X	
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany	X	
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany	X	
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland	X	
NB 0197	TÜV Rheinland LGA Products GmbH	Germany	X	
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany	X	X

03/12/2020

Nordic Alliance
for Clinical Genomics