Direktoratet for e-helse

JIC

Joint Initiative Council

Standardiseringsutvalget 04.06.21, VH

Joint Initiative Council, JIC

Organization

- » Missions & Values
- » What we do
- » Who is who
- » San Francisco Declaration
- » Maringa Manifesto

Documents

- White Paper
- Projects
- Calendar
- Meeting Agendas & Minutes
- Tools

Missions and Values

Promote interoperability and seek to **avoid overlaps and inconsistencies** between standards used in health informatics (Facilitation)

Achieve greater coordination and consistency of health informatics standards development (Flexibility)

Develop global awareness of the importance and potential contribution of health informatics standards (Customer Focus)

Share information transparently on opportunities and needs for health informatics standardization (Openness & Transparency)

Provide a gateway to support and provide advice on health informatics standards collaboration and for reporting progress toward achieving a coherent set of standards for health informatics (Respect for professionalism)

Promote development, adoption and recognition of relevant health informatics standards as international standards (Innovation & Quality Improvement)

JIC

Executive council meetings take place virtually during the COVID-19 crisis.

JIC Open Forum 23.02.21

Topic	Joint Initiative Council Open Forum - Afternoon Session
Description	Transcending national boundaries and organizations, the Joint Initiative Council's standards development organizations work collaboratively to provide global, coordinated—not competitive—standards that address real-world healthcare issues. In its recently released white paper, the JIC explores the desired future of a digital health ecosystem where high-quality data is available to the right people, at the right place and at the right time for high-quality decisions and care.

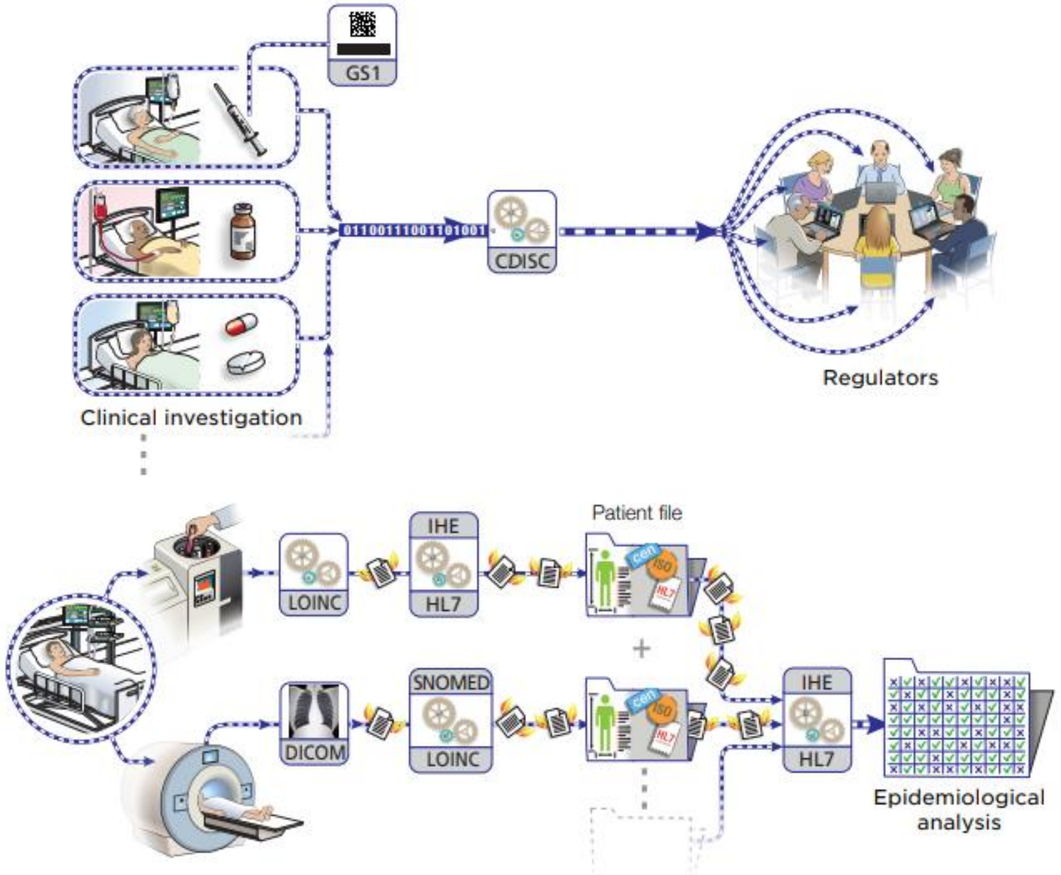
Afternoon Session – Enabling the digital transformation of healthcare
AEDT 3am-4:30am | PST 8am-09:30am | EST 11am-12:30pm | CET 5pm-6:30pm

- Introduction – Mike Nussbaum, past chair, IHE International
- COVID-19 case – Speaker to be confirmed
- International Patient Summary (IPS) – Robert Hausam, HL7 International and Steve Kay, CEN TC 251
- Identification of Medicinal Products (IDMP) – Speaker to be confirmed
- Genomics – Bron Kisler, ISO TC 215, SC 1

JIC whitepaper, 2021

Viser hvordan organisasjonene jobber sammen på utvalgte områder

COVID



Today, JIC members are contributing to the COVID-19 public health need, either by addressing immediate gaps or by providing their existing standards, to include:

- CDISC released the *Interim User Guide for COVID-19*.
- DICOM provides existing imaging standards.
- GS1 enables the tracking and tracing of supplies.
- HL7 International is developing several new implementation guides and projects to address new COVID-19 use cases, and define and incorporate essential new data elements and terminologies into its Fast Healthcare Interoperability Resources (FHIR) standard.
- IHE International provides profiles to ease the adoption of standards, as well as assessment procedures for strong conformity, (e.g., Connectathon).
- ISO TC215 and CEN TC251 are integrating the new need into their standards for implementation.
- SNOMED International and LOINC provide electronic health data elements.

IPS

Each of the participating SDOs contributes its specific expertise and standards capabilities, to include:

- CEN TC251 provides the reference standard for conformant implementation guides.
- GS1 and DICOM provide their existing standards and solutions.
- HL7 International delivers FHIR and CDA implementation guides.
- IHE International provides profiles and conformance testing.
- ISO TC215 is transitioning the European-focused IPS to become a truly global standard.
- SNOMED International provides access to clinical terminologies to support IPS.

"This unprecedented JIC collaboration has demonstrated how, when working together, standards can be produced that have broad clinical and industry support, and more global opportunities for implementation."

– **Michael Nusbaum**, IHE International

"This unprecedented JIC collaboration has demonstrated how, when working together, standards can be produced that have broad clinical and industry support, and more global opportunities for implementation," explains Michael Nusbaum with IHE International.

"The IPS is essential data about a patient's healthcare, that can be made available whenever and wherever it is needed for their treatment. It will effectively provide an information bridge from their home healthcare system to another, thereby, supporting continuity of care."

– **Stephen Kay**, CEN TC251

IDMP

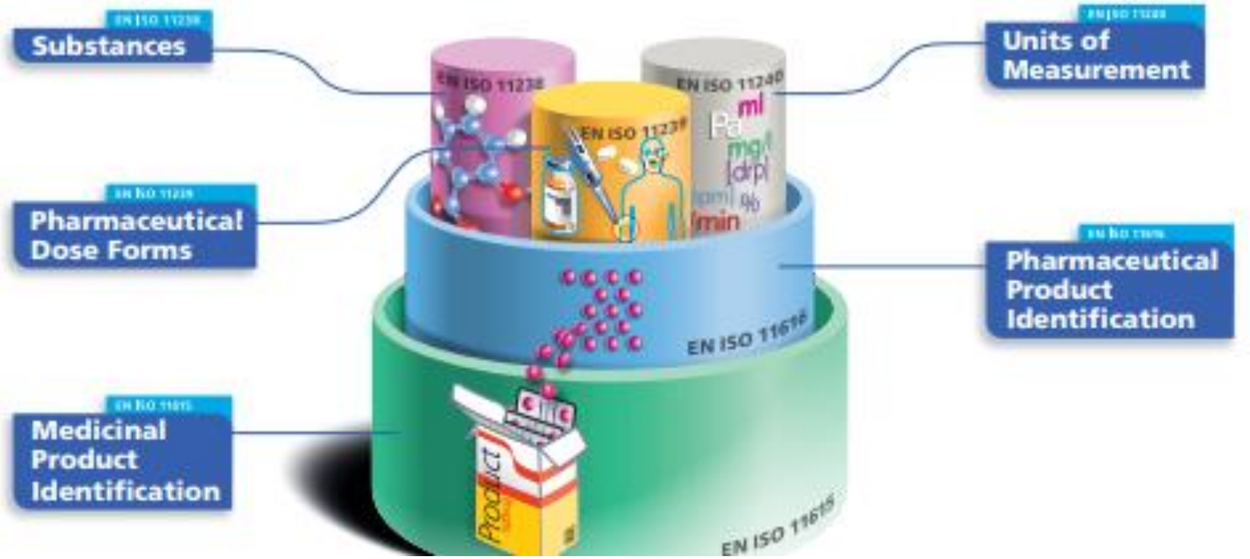
Working together, the SDOs produced the IDMP suite of standards that uniquely identify and describe medicinal products for the consistent documentation, coding and exchange of product information between global regulators, manufacturers, suppliers and distributors.

Each SDO contributes an element of the IDMP solution, to include:

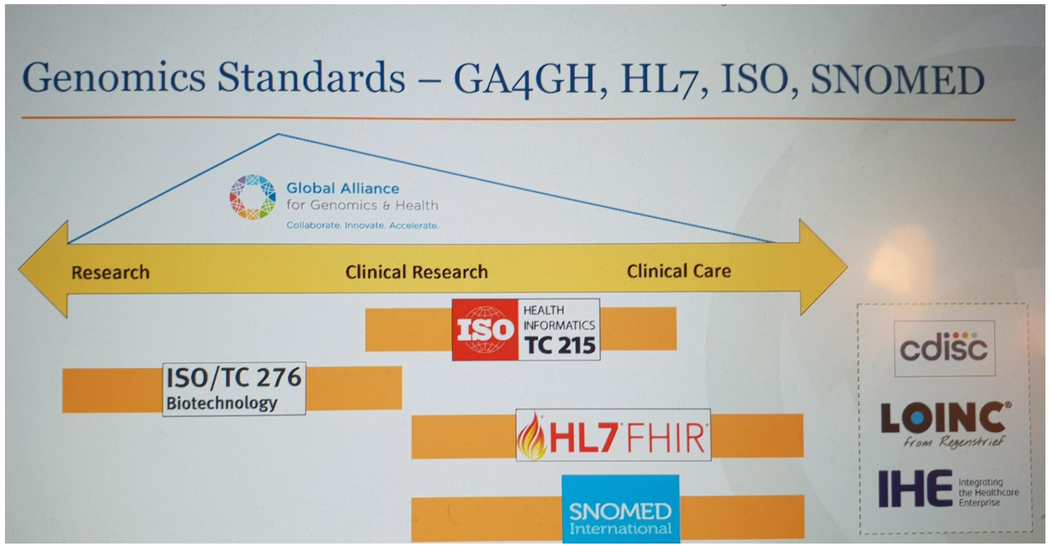
- CDISC integrates IDMP in its standards for clinical studies.
- CEN TC251 and ISO TC215 deliver the information architecture.
- GS1 provides the link to the physical products and supply chains.
- HL7 International provides the standards to communicate and store information.
- SNOMED International maps its terminologies to bridge regulatory and clinical needs.

"IDMP standards help facilitate regulatory activities such as pharmaceutical development and registration, life cycle management of medicinal products, pharmacovigilance and risk management. The standards can also be applied to clinical needs, such as for prescriptions, medicinal product comparisons in case of shortages, and much more."

– **Christian Hay**, GS1 Healthcare



Genomics



- The Global Alliance for Genomics & Health (GA4GH), a liaison to the ISO Genomics Sub-Committee, is contributing with subject matter experts.
- HL7 International is developing standard tools to structure and communicate genomics information.
- ISO TC 215 has formed the Genomics Informatics Sub-Committee and other liaison committees are contributing expertise—ISO/TC 276, ISO/IEC, JTC1/SC29 and IHE International.
- LOINC is providing laboratory terminologies.
- SNOMED International is offering clinical terminologies.

"As the field of genomics continues to grow, the use of reliable, high-quality global data standards is imperative. Various genomics standards are needed in genomics data processes and workflow—from data production to clinical application."

– **Bron Kisler**, ISO TC215, SC1

Direktoratet for e-helse

Direktoratet for e-helse

Europeisk koronasertifikat – utvikling og standarder

Espen Stranger Seland


Styring og forvaltning av samhandling
Juridisk samhandlingsevne
Organisatorisk samhandlingsevne
Semantisk samhandlingsevne
Teknisk samhandlingsevne
Styring og forvaltning av integrerte offentlige tjenester

Forutsetninger for semantisk samhandlingsevne

Felles informasjonsmodeller

Felles begrepsdefinisjoner, kodeverk og terminologi

Felles format og syntaks for utveksling

eHealth Network

- Medlemmer fra alle medlemsland i EU og Norge (observatør)
- Frivillig nettverk av e-helsemyndigheter
- Fokuserer på pasienters helserettigheter på tvers av landegrenser
- Utvikler veiledere, spesifikasjoner

- Arbeidsgrupper
  - eHN Contact tracing apps
  - EU Digital COVID Certificate
- Undergrupper

COVID-19!

Hovedanvendelser

- Utveksling av medisinsk informasjon
- Fri bevegelse i Europa (reise)

Tidslinje

- Desember 2020: European Council: Call for «*a coordinated approach to vaccination certificates*»
- Mars 2021: Europakommisjonen foreslår en lovtekst for *Digital Green Certificate*
- Mai 2021: *EU Digital COVID Certificate* (DCC) godkjent i EU-parlamentet
- Juli 2021: DCC tilgjengelig i EU

Anvendelse

- (…) *the possible need for a person to receive and present a vaccination certificate.*
- *It is up to the Member States to decide on the purposes and use of vaccination certificates.*
- Utvidet med testresultat og immunitet gjennom sykdomsforløp

Leveranser:

- Minimum datasett
- Unik vaksinasjonssertifikat/identifikator
- Tillitsrammeverk

Undergrupper i eHealth Network

- eHN sg Semantics
- eHN sg Technical Interoperability
  - Business rules, FHIR, sikkerhet, etc.

- Deltagelse fra Direktoratet for e-helse, NHN og FHI

Høynivå informasjonsmodell

- Regnearkmetoden
- Hovedgrupper av informasjon
  - Eksempler: Person, vaksineinformasjon, metadata
- Attributter
  - Eksempler: Personnavn, vaksinetype, vaksinasjonsland...
- Foretrukket kodeverk
  - Eksempler: SNOMED CT, ATC, ISO 8601, HL7 FHIR

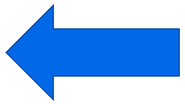
Annex 1 – Minimum dataset for vaccination certificate

Section	Data element	Description	Preferred Code System
Person identification (minimum dataset)	Person name	The name of the person vaccinated	
	Person identifier (optional)	An identifier of the person vaccinated, according to the policies applicable in each country Examples: citizen ID card or identifier within the health system/IIS/e-registry	
	Person date of birth (optional)	Person's date of birth. Mandatory if no *Person identifier* is provided.	ISO 8601 or other international stated format
Vaccination information (minimum dataset)	Vaccine	Generic description of the vaccine/Vaccine component(s) *Example:* *J07BX03 covid-19 vaccines (temporary code, to be implemented in ATC 2022)* *1119349007 | COVID-19 mRNA vaccine |* *1119305005 | COVID-19 antigen vaccine |*	SNOMED CT and ATC Classification (J07 therapeutic subgroup); In the future substances from the ISO IDMP Implementation-EU-SRS system
	Vaccine medicinal product	Medicinal product name *Example:* *COMIRNATY concentrate for dispersion for injection*	For the time being, this should be the name of the medicinal product as registered in the country. In the future the information on the medicinal product can incorporate the identifiers from the implementation of the ISO IDMP Standards and the medicinal package's unique identifier
	Marketing Authorization Holder	Marketing Authorisation Holder *Example:* *Pfizer BioNTech*	EMA's Organisations System data (SPOR)
	Number(s) in a series of vaccinations / doses	Order in the vaccination course *Example:* *1 out of 2*	
	- Batch/lot number(s)	A distinctive combination of numbers and/or letters which specifically identifies a batch	
	- Date(s) of vaccination		ISO 8601 or other international stated format

…til detaljer

- Minimum datasett for
  - *Verifiable vaccination certificates*
  - *COVID-19 citizen recovery interoperable certificates*
  - *COVID-19 test result certificates*
- Detaljerte verdisett for kodeverk
- Syntaks og format:
  - JSON Schema for bruk i QR-koder
  - FHIR-profiler (IG), basert på bl.a. IPS
  - Papirutskrift!

Felles informasjonsmodeller



Felles begrepsdefinisjoner, kodeverk og terminologi

Felles format og syntaks for utveksling

[eHealth and COVID-19 | Public Health (europa.eu)]

Teknisk samhandlingsevne - standarder

- RFC 4627 JavaScript Object Notation (JSON)
- RFC 8392 CBOR Web Token (CWT)
- CBOR RFC 8152 Object Signing and Encryption (COSE)
- Base45 (draft)
- ISO/IEC 18004:2015 QR Code bar code symbology specification
- ISO/IEC 14888–3:2006 ECDSA, signeringsalgoritme
- ISO/IEC 10118–3:2004 Dedicated hash-functions
- RFC 1950 + 1951 ZLIB, komprimering

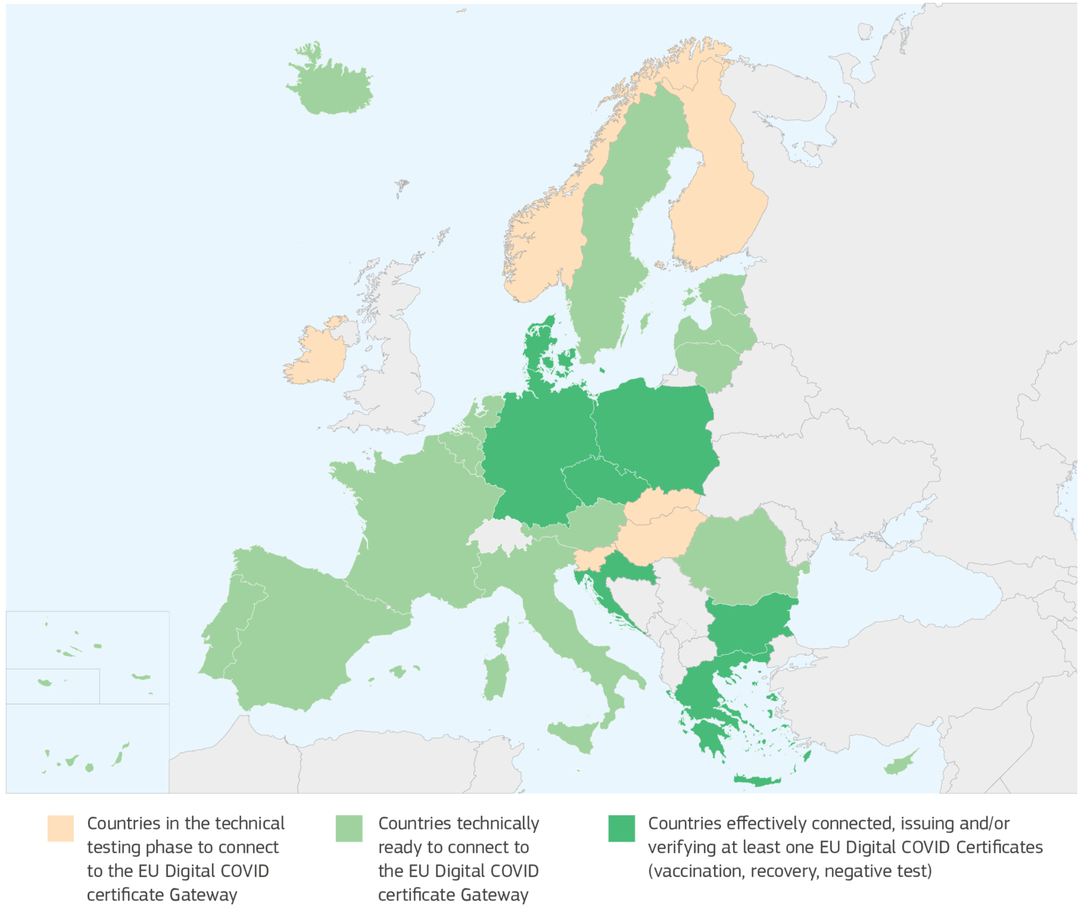
Erfaringer

- Sette sammen team etter samhandlingslag (EIF) fungerer godt
- En smidig tilnærming funger bra når

  …oppdraget og premissene er uklare

  …fag, detaljer, jus etc. er i uferdig eller i bevegelse

  …man har dårlig tid!



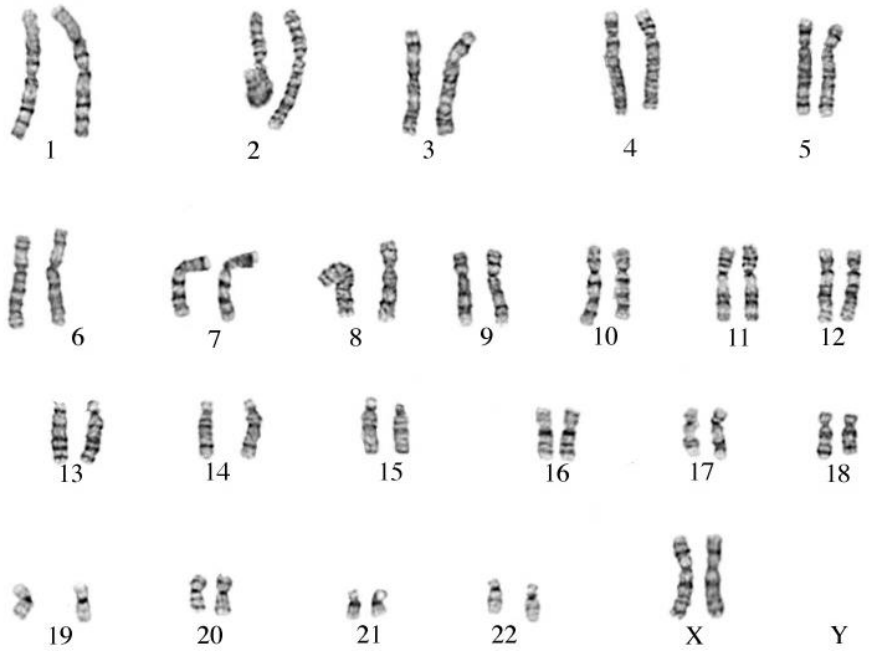
ISO/TC 215/SC1

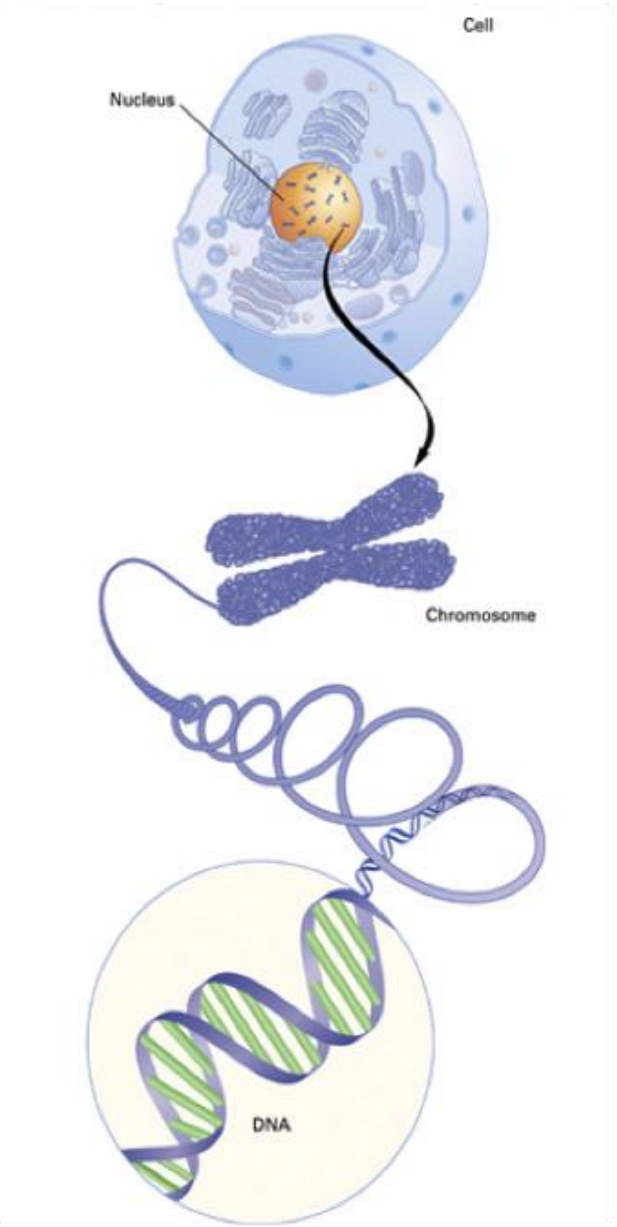
Genomics informatics

Sharmini Alagaratnam (DNV), Evita Maria Lindholm (Dir e-Helse)

03 June 2021

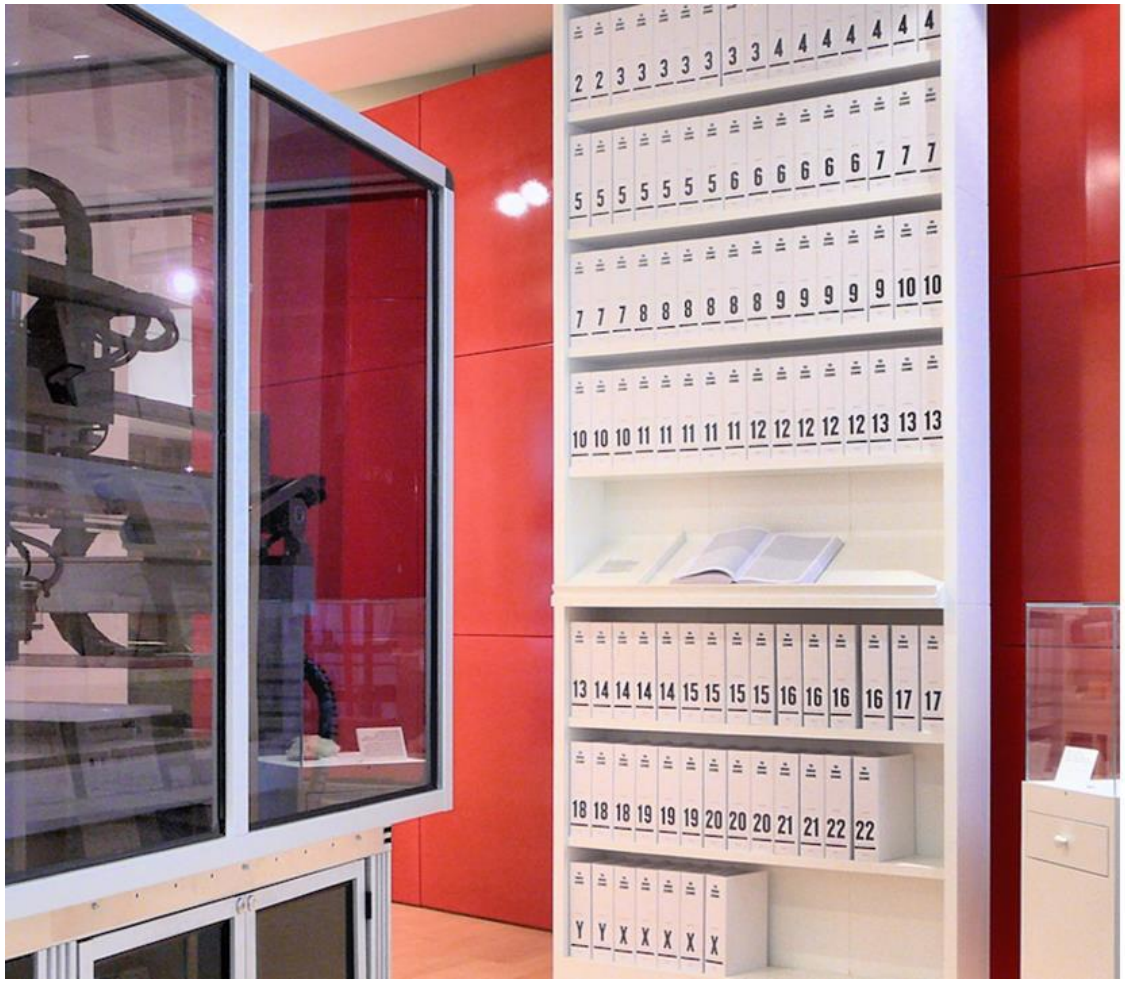
Hva er genomikk og hvorfor er det viktig?

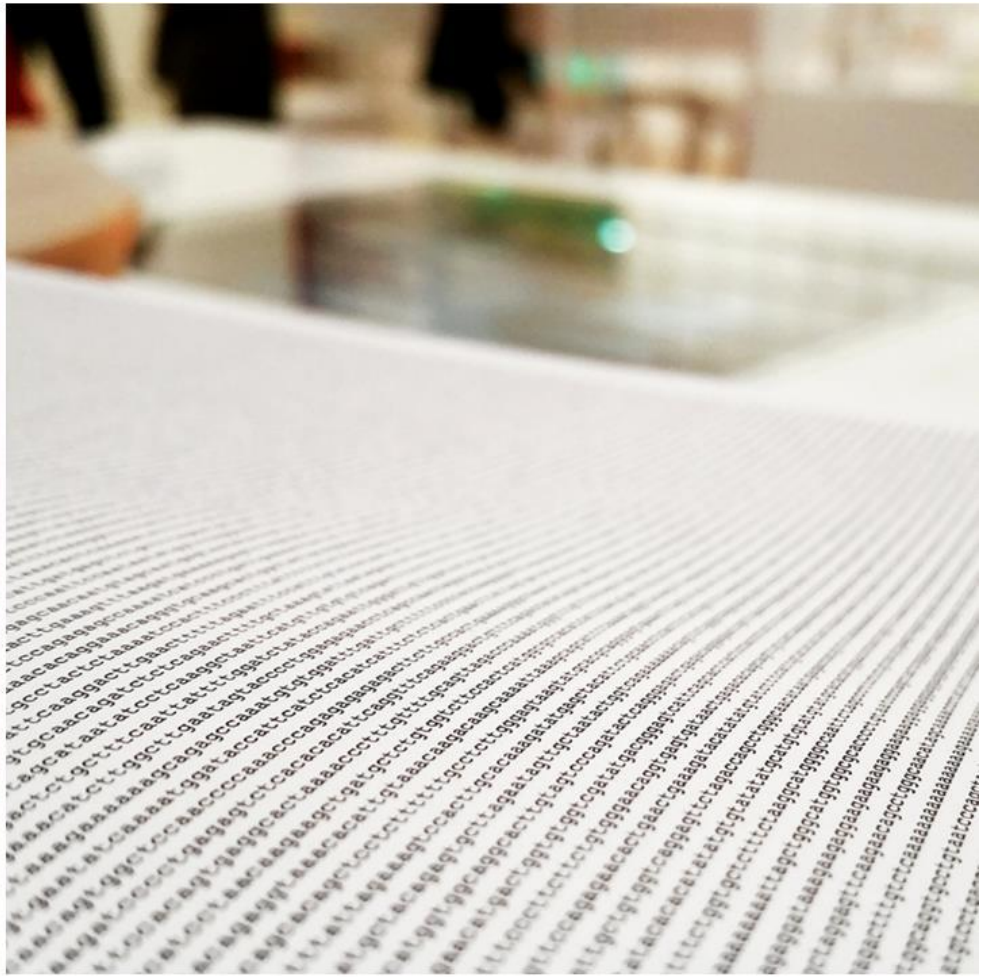




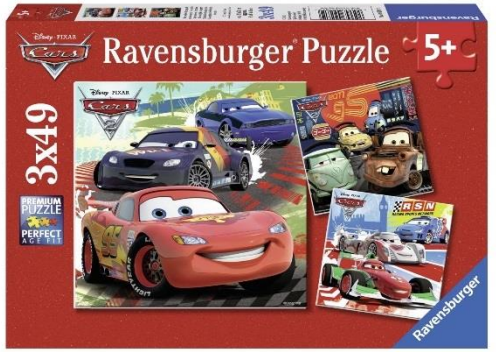
- The human genome consists of 3 billion base pairs consisting of A, G, C and T
- Arranged in 23 chromosome pairs

Hvordan ser en genom ut på papir?

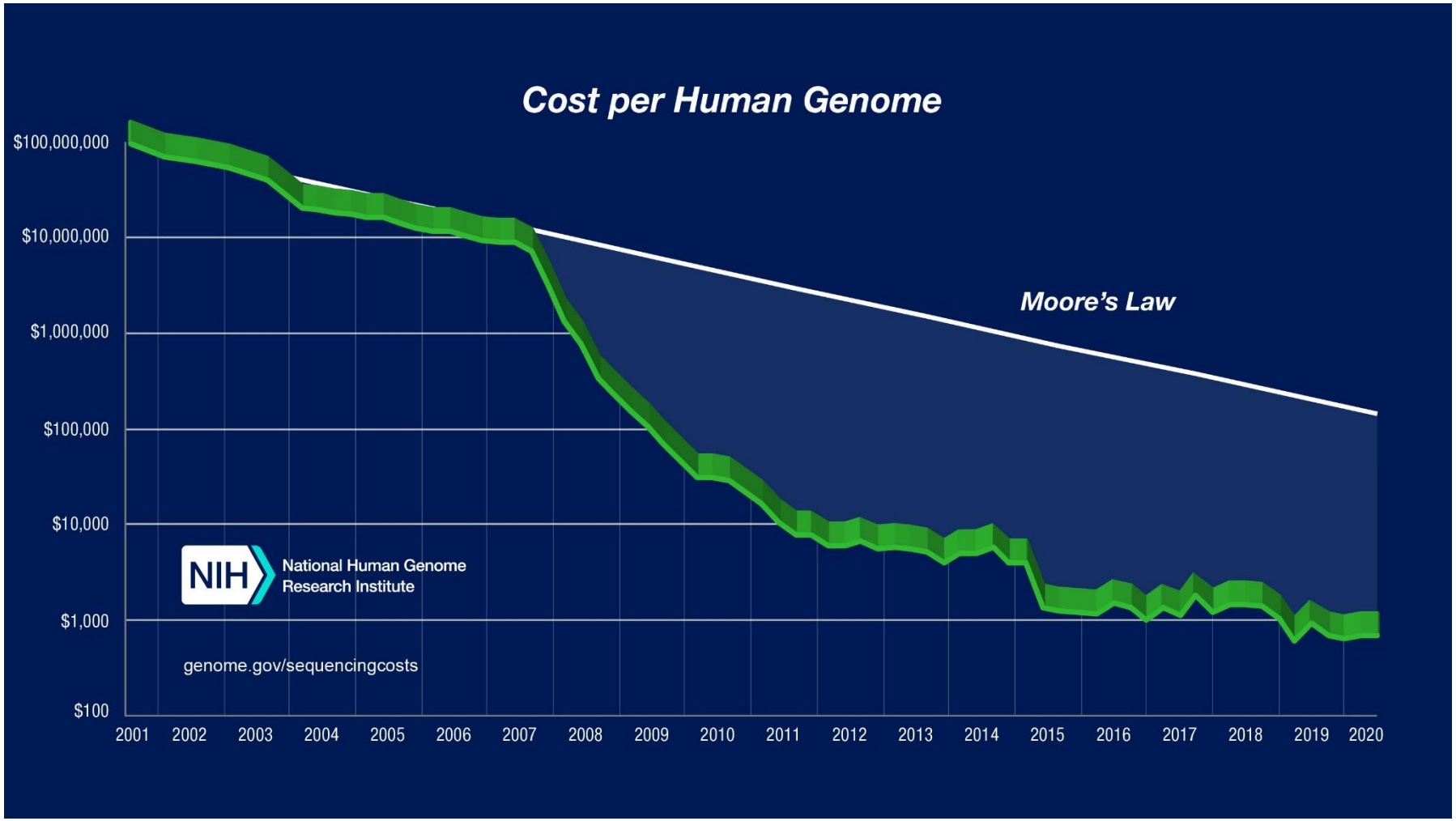




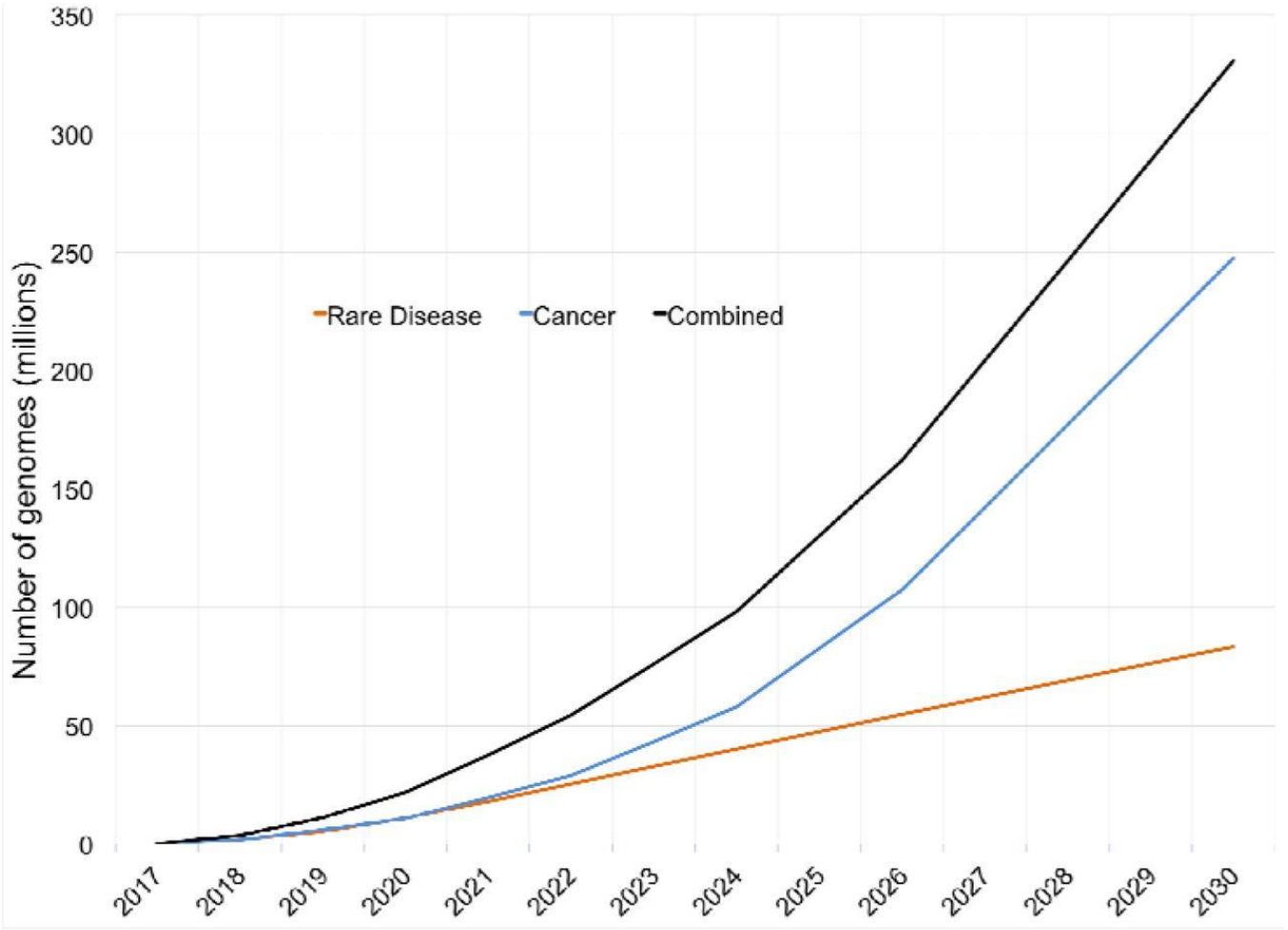
High-throughput sequencing in 1 minute



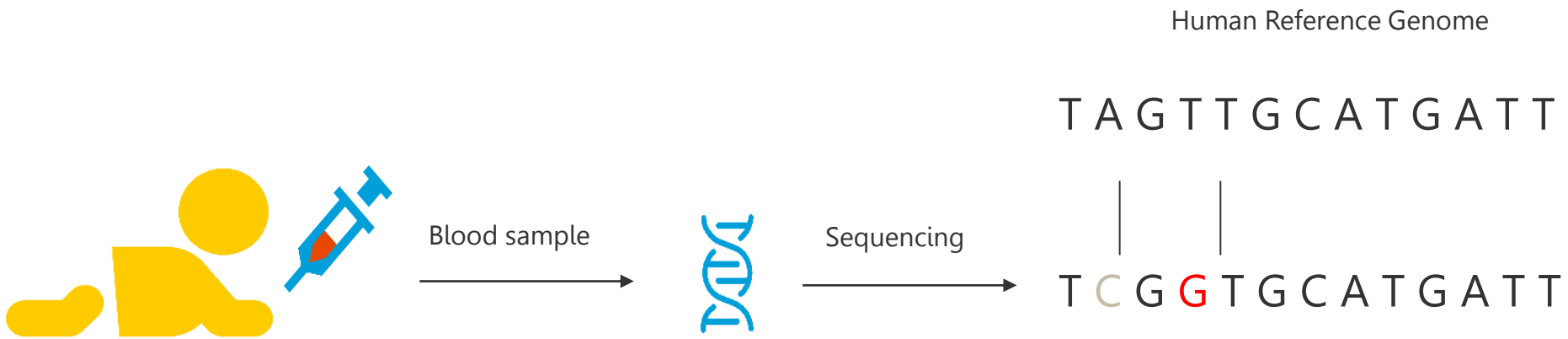
Pris på sekvensen av en human genom

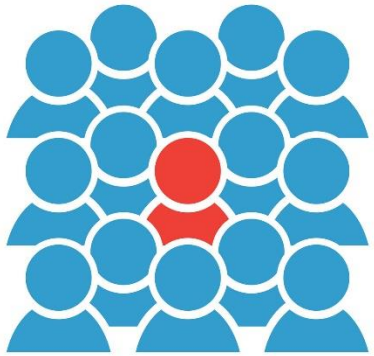


Vekst i antall sekvenserte humangenomer



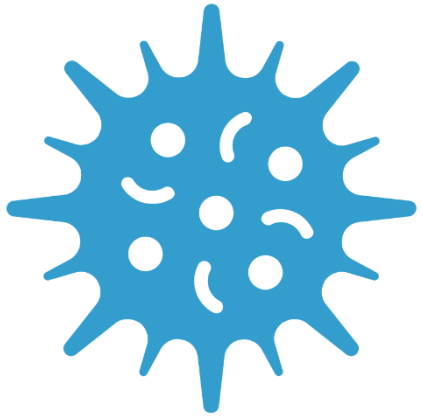
Bruksområder



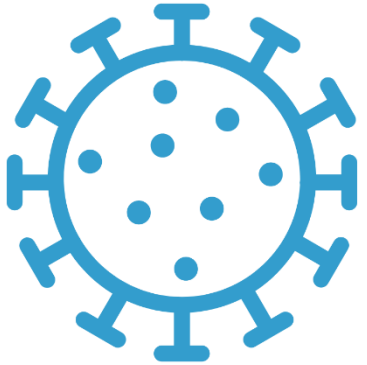


Sjeldne sykdommer

Folkesydommer



Kreft – disposisjon & persontilpasset terapi

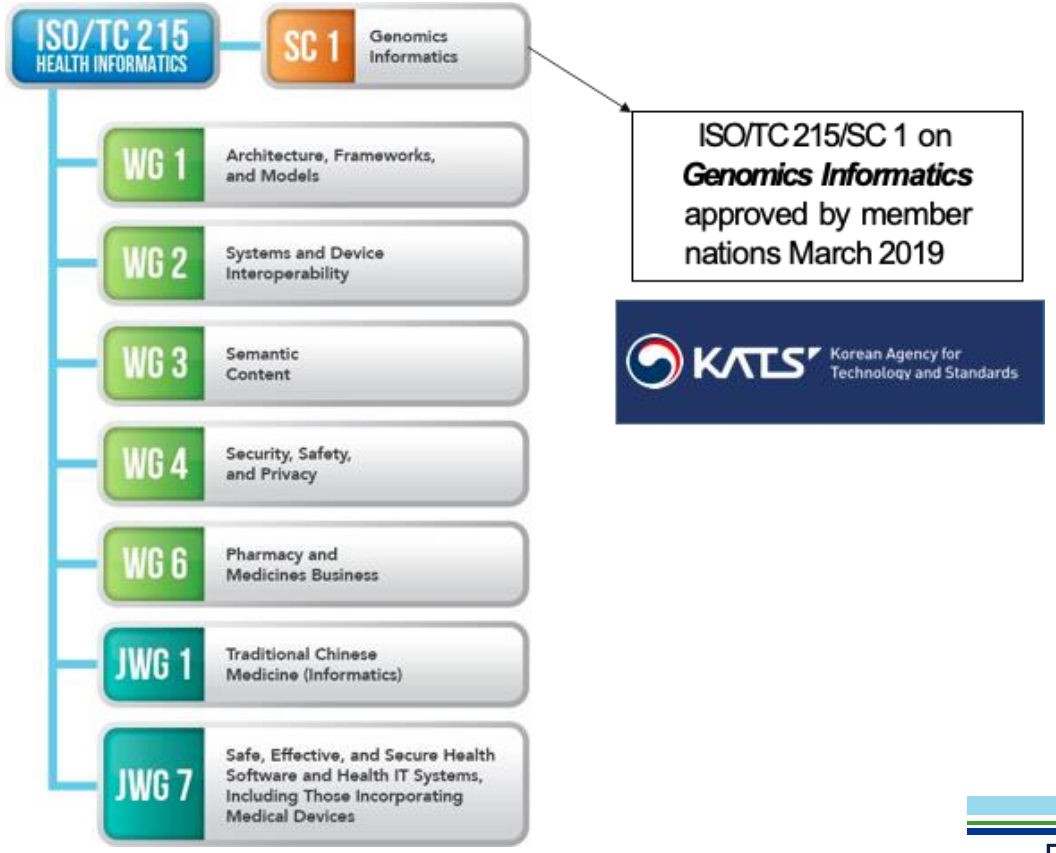


Smittsomme sykdommer

ISO/TC 215/SC1 Genomics informatics: Scope

- Standardization of computable data, information, and knowledge, including their representation and metadata, for the application of omics, including but not limited to genomics, phenomics and proteomics, to support human health and clinical research.

- 4 plenarymøter så langt:
- Nov 2019 Daegu
- Apr 2020 Virtuell
- Nov 2020 Virtuell
- Apr 2021 Virtuell



Strukturen: 2 Task forces, 1 Working group

REFERENCE ↓	TITLE
ISO/TC 215/SC 1/TF 1	Strategic roadmap
ISO/TC 215/SC 1/TF 2	Cross-SDO genomics coordination
ISO/TC 215/SC 1/WG 1	Genomics data sharing

3 publiserte standarder

STANDARD AND/OR PROJECT UNDER THE DIRECT RESPONSIBILITY OF ISO/TC 215/SC 1 SECRETARIAT (3)	STAGE
ISO/TS 20428:2017 Health informatics — Data elements and their metadata for describing structured clinical genomic sequence information in electronic health records	90.92
ISO/TS 22692:2020 Genomics informatics— Quality control metrics for DNA sequencing	60.60
ISO 25720:2009 Health informatics — Genomic Sequence Variation Markup Language (GSVML)	90.93

9 standarder under utvikling

STANDARD AND/OR PROJECT UNDER THE DIRECT RESPONSIBILITY OF ISO/TC 215/SC 1 SECRETARIAT (9)	STAGE
ISO/AWI TS 4424 Genomics Informatics— Data Elements and their Metadata for Describing the Tumor Mutation Burden (TMB) Information of Clinical Massive Parallel DNA Sequencing	20.00
ISO/AWI TS 4425 Genomics Informatics — Data elements and their metadata for describing the microsatellite instability (MSI) information of clinical massive parallel DNA sequencing	20.00
ISO/CD 4454 Genomics Informatics — Phenopackets: A Format for Phenotypic Data Exchange	30.99
ISO/AWI TS 20428 Health informatics — Data elements and their metadata for describing structured clinical genomic sequence information in electronic health records	10.99
ISO 21393 Genomics informatics — Omics Markup Language (OML)	60.00
ISO/CD TR 21394.2 Genomics informatics — Whole Genomics Sequence Markup Language (WGML)	30.99
ISO/DTS 22690 Genomics informatics — Reliability assessment criteria for high-throughput gene-expression data	30.99
ISO/TS 22693 Genomics informatics — Structured clinical gene fusion report in electronic health records	60.00
ISO/CD TS 23357 Genomics Informatics - Clinical genomics data sharing specification for next generation sequencing	30.99

DNV

Liaison partnere

GA4GH: Global Alliance for Genomics and Health

ISO/TC276: Biotechnology

ISO/IEC JTC1/SC29: Coding of audio, picture, multimedia and hypermedia information

SNOMED Int'l: NGO for SNOMED CT, a codified language to represent groups of clinical terms

EU-STANDS4PM: H2020 CSA – a standardization framework for data integration and data-driven *in silico* models for personalised medicine

INSTAND-NGS4P: H2020 Pre-Commercial Procurement project

HL7 (ikke formalisert): standards for the exchange, integration, sharing and retrieval of electronic health information

SC1 Roadmap Background

- Task Force Developments

• Launched at Daegu, • Co-Leads Bron Kisler and Don Newsham	Nov 2019
• Starting Points and Views Presented	March 2020
• Updated Roadmap Views with Ecosystem	November 2020
• Drafting and Authoring Team Identified	November 2020
• Author Team Roadmap Development	December 2020 to May 2021

Complete draft ready for fall 2021 SC1 meetings

SC1 Roadmap

Purpose

- Purpose
  - provide guidance on the types, needs and opportunities for genomics informatics standards
  - better coordinate and collaborate on standards development between national members bodies, the medical and research communities and other SDO's
  - provide a clear and cohesive view for engagement and collaboration with genomics experts from around the world
  - serve as a communication tool for the leaders of SC1, all the national member bodies of SC1 and all interested genomics informatics communities

All to achieve better health and care through standards in genomics informatics.

Cross SDO Considerations

	GA4GH	HL7	ISO SC1 (TC215)	ISO/TC 276
1. Data Production	✓			✓
2. Processing; Event Detection				✓
3. Filtering; Review; Validation			✓	
4. Annotation; Functional Prediction	✓		✓	
5. Interpretation; Report Generation		✓	✓	
6. Clinical Application		✓	✓	
7. Data Sharing	✓	✓	✓	
8. Security; Data Access	✓			

SC1 møte 26. & 27. april 2021

- 3 standarder publisert
- Ingen nye arbeidspunkter
- Pågående arbeid på 7 standarder diskutert
- En ny introdusert: PWI Genomics Informatics – Genomics Data Sharing Platform: Principles & Requirements (Canada)

Takk og spørsmål

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Direktoratet for e-helse

Veileder for standarder ifm Digital Hjemmeoppfølging

Standardiseringsutvalget 04.06.21, VH

Forankret i plan for internasjonal standarder 2021-2024

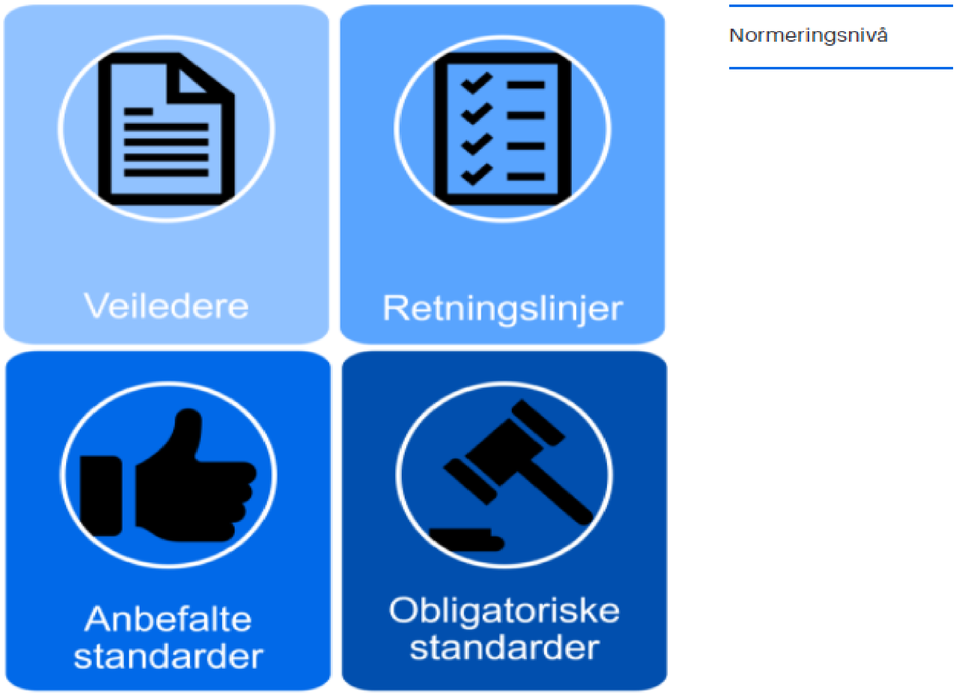
Velferdsteknologi og digital hjemmeoppfølging			
2021	2022	2023	2024
Veileder for HL7 FHIR for VFT/DHO	**Retningslinje** for standarder for VFT/DHO	**Veileder for** medisinsk-teknisk utstyr	**Anbefalte standarder** for VFT/DHO

Planlagt å utarbeide normerende produkter på gradvis høyere normeringsnivå

Normerende dokumenter

Direktoratet for e-helse publiserer normerende dokumenter som gir rammer og retningslinjer for IKT-utviklingen i helse- og omsorgssektoren. De normerende dokumentene er kategorisert på fire nivå:

- **Veiledere:** Gir råd innen spesifikke områder basert på beste praksis fra flere virksomheter
- **Retningslinjer:** Beskriver nasjonale myndigheters oppfatning av hva som er god praksis innenfor et område
- **Anbefalte standarder:** Standarder anbefalt av offentlig myndighet, med intensjon om at de skal bli obligatoriske
- **Obligatoriske standarder:** Standarder som er hjemlet i forskrift. Dette er bindende normer



Veileder på laveste normeringsnivå

Veileder for bruk av HL7 FHIR områdeprofiler for velferdsteknologi og digital hjemmeoppfølging

- **Skal tilrettelegge for bruk av felles områdeprofiler innen velferdsteknologi**
- **Skal sette retning og beskrive implementering**
- **Områdeprofiler utarbeides av velferdsteknologiprogrammet**
- **Eksempler på mulige områdeprofiler: Encounter, Vital Signs, Care plan og composition**

Metode for utvikling av HL7 FHIR områdeprofiler

Utgiver: Direktoratet for e-helse | ID: HITR 1241:2021 | Normeringsnivå: Veileder

Veileder om hvordan norske områdeprofiler for HL7 FHIR skal utvikles, normeres og vedlikeholdes

Innledning

Veilederen beskriver en metode for hvordan norske områdeprofiler for HL7 FHIR skal utvikles, normeres og vedlikeholdes.

Formål og bruksområde

Veilederen beskriver hvordan HL7 FHIR kan tilpasses norske anvendelser, behov og krav. Metoden er en åpen og smidig prosess som skal sikre at profilene holder høy kvalitet og forankres hos alle relevante aktører i sektoren. De ferdige områdeprofilene blir publisert som normerende produkter (veiledere, retningslinjer og standarder).

Metoden er basert på utviklingsmetoden for HL7 FHIR, Direktoratet for e-helses forvaltningsmodell for normerende produkter og profileringshierarkiet

Veilederen er også tenkt å favne bredere enn FHIR

- Internasjonale standarder er supplerende og det er aktuelt å se på sammenhengen mellom HL7/FHIR områdeprofiler og andre internasjonale standarder som er relevant for DHO/velferdsteknologi
- Standarder kan relateres til ulike nivå i EIF-modellen
- Standarder til bruk innen DHO kan også ha sitt opphav i andre standardiseringsorganisasjoner enn CEN eller ISO

Relevante standarder under ISO/TC215

Personalized medicine

- Foreløpig kun Task Force
- Mye fokus på innbygger og innbyggers journal

Standarder for samhandling med i utstyr kan være tilknyttet WG2 (Systems and Device Interoperability)

ISO/TC 215/JWG 7	Joint ISO/TC 215 - IEC/SC 62A WG: Safe, effective and secure health software and health IT systems, including those incorporating medical devices

Ønsker innspill til arbeidet med veileder

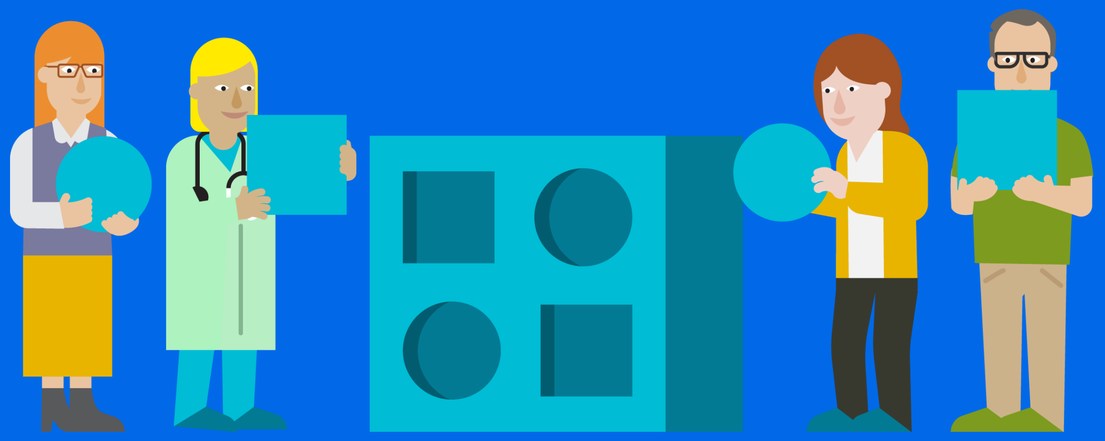
- Hvor trykker skoen mest?
- Erfaringer fra DHO/velferdsteknologi i utvalget
  - Prosjekter som kan være aktuelle for å bruke veilederen
  - Prosjekter som har nyttig erfaring
  - Ressurspersoner som kan gi nyttige innspill til arbeidet
- Noen som er involvert i standardiseringsarbeid i ISO eller andre organisasjoner som kan være relevant for veilederen?
- Noen som kan være interessert i å delta i arbeidet med veileder?

Direktoratet for e-helse

Direktoratet for e-helse

Roller og ansvar

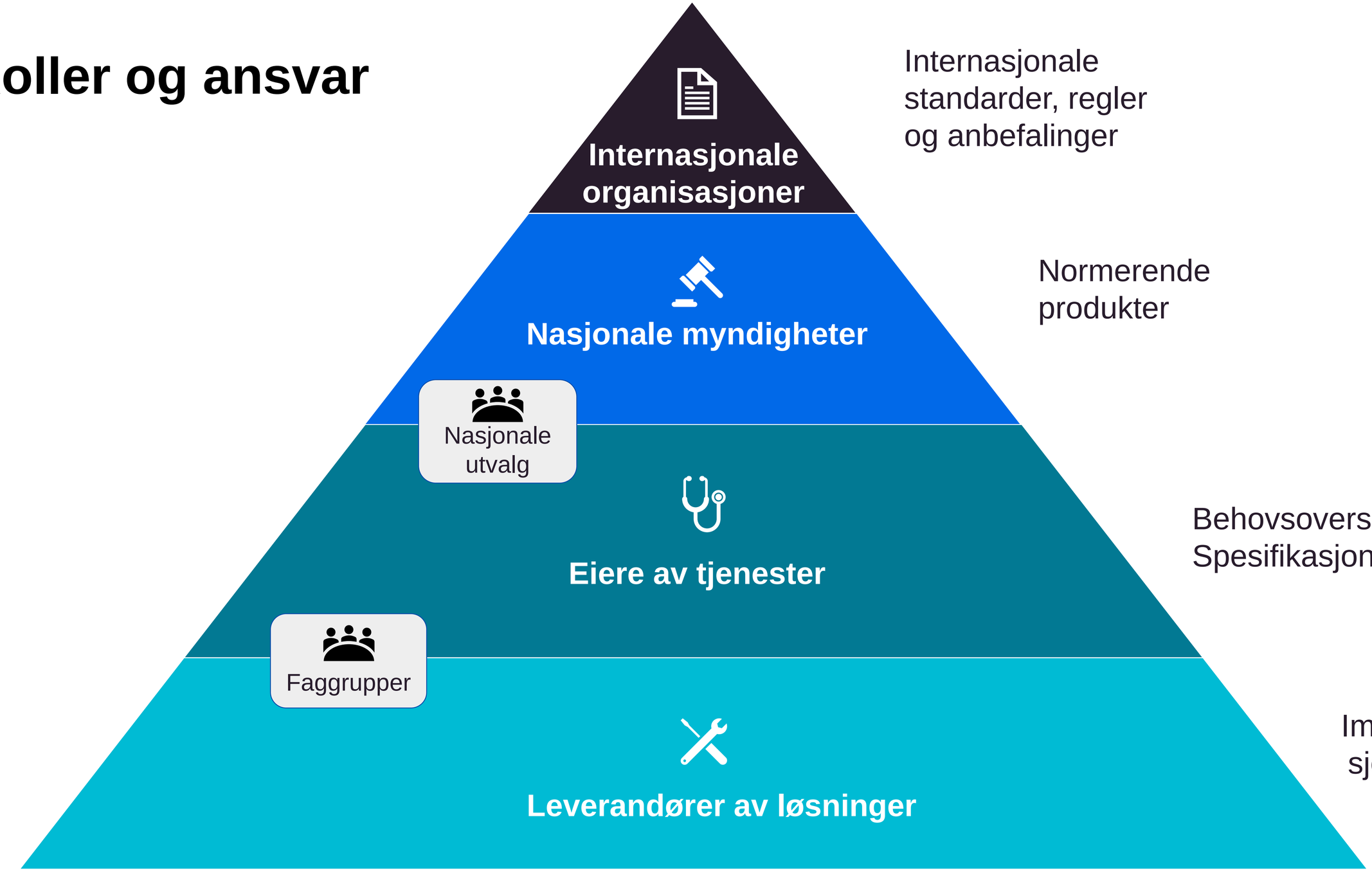
Standardiseringsutvalget 4. juni 2021



Hvorfor trenger vi å tydeliggjøre ansvar og roller?

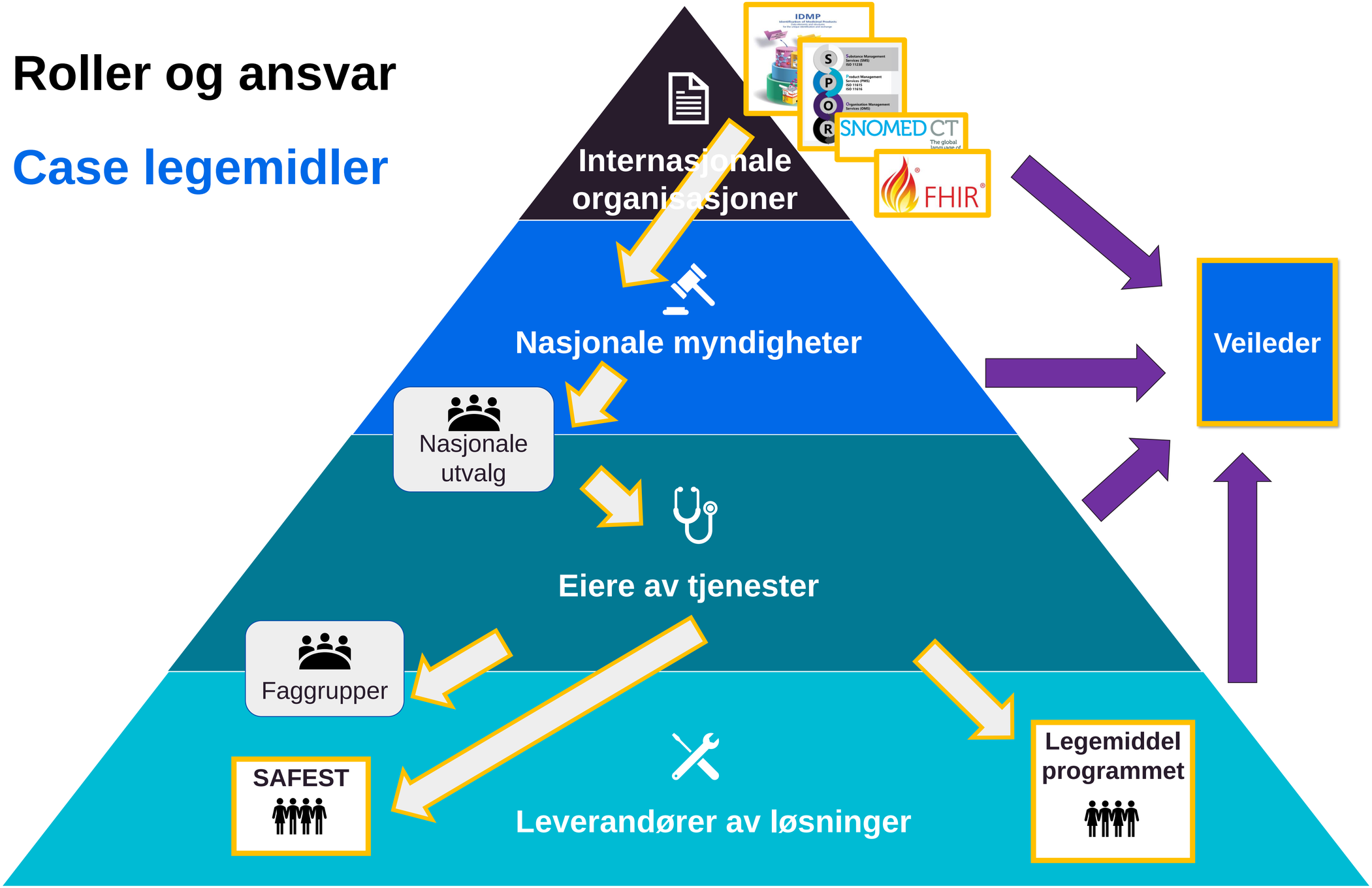
- **Standardisering skjer mer distribuert og er basert på smidig utvikling**
- **Økt bruk av internasjonale standarder gir flere relasjoner på internasjonale arenaer**
- **Tilrettelegge for økt innovasjon**
- **Forutsigbarhet og avklarte forventninger til hvem som gjør hva**

Roller og ansvar



Roller og ansvar

Case legemidler



Plan for internasjonale standarder

Roller og ansvar			
2021	2022	2023	2024
Utarbeide ansvarsmodell	**Operasjonalisere** ansvarsmodell	**Ferdigstille og normere** ansvarsmodell	

Sammenheng med forvaltningsmodell

Forvaltningsmodell for normerende produkter

Roller og ansvar internasjonale standarder

Drøfting

- Hvordan kan vi best videreutvikle og begynne å prøve ut modellen?
- Kjenner man til internasjonalt arbeid som er relevant for arbeidet med roller og ansvar?
- Hvordan kan standardiseringsutvalgets medlemmer bidra i det videre arbeidet?

Vedtak

Standardiseringsutvalget tar saken til orientering og ber Direktoratet for e-helse ta med innspill framkommet i møtet i det videre arbeidet. Virksomheter som påtar seg oppgaver, følger opp sine punkter og gir tilbakemelding til utvalget.