

Regionernes arbejde med European Health Data Space, udfordringer og implikationer

E-sundhedsobservatoriets årskonference, 7/10-2026

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Medlem af Regionernes it-arkitekturråd RITA

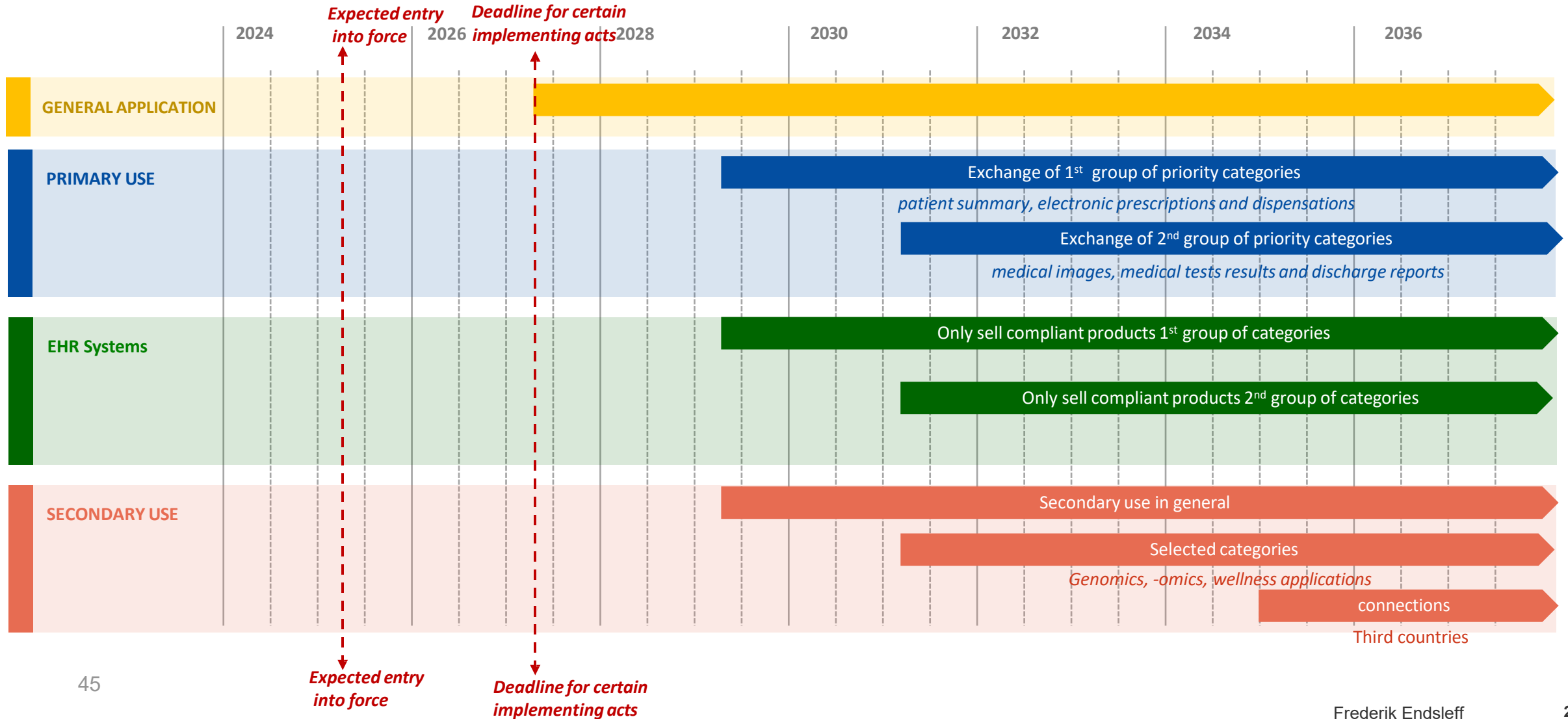
Medlem af Sundhedsdatastyrelsens rådgivende udvalg for standarder og arkitektur RUSA

Formand for DS-udvalg S-273 Sundhedsinformatik

Medlem af FDA porteføljegruppen under Digitaliseringsstyrelsen

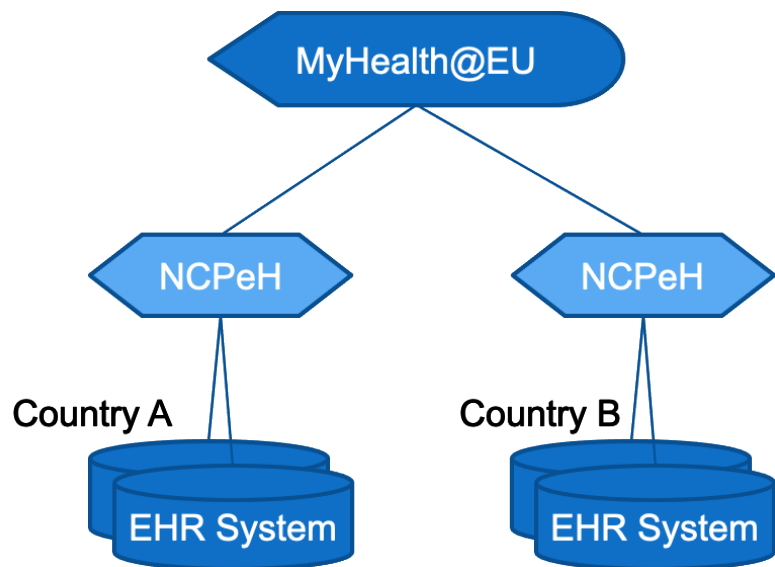
EHDS – Overall timeline for application

Article 105

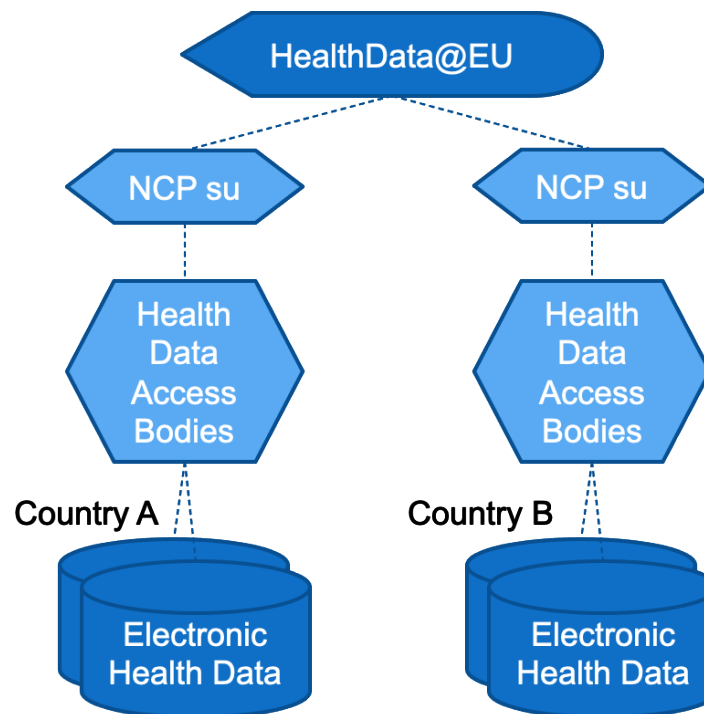


Tre hovedområder

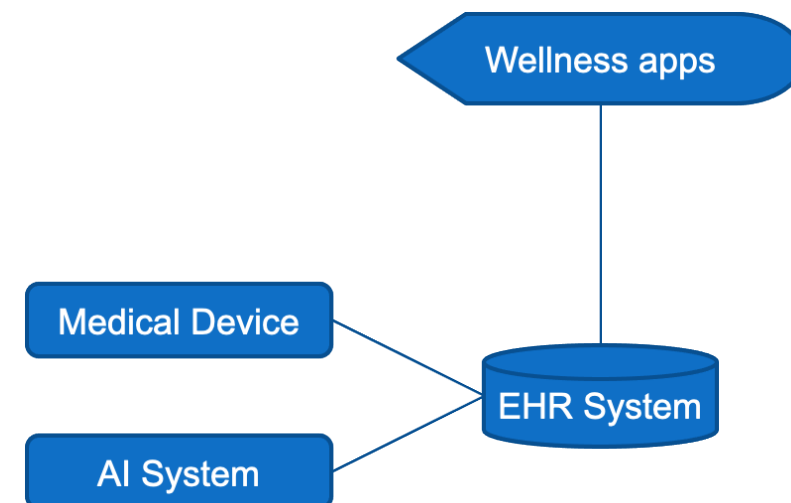
Primær anvendelse



Sekundær anvendelse



EPJ systemer og interoperabilitet



CEN og ISO standarder ift EHDS

- General requirements
 - EN ISO/HL7 10781 EHR System Functional Model
 - CEN ISO/TS 82304-2 Quality and Reliability of Health and Wellness Apps
 - EU Harmonised standards in support of the Medical Device Regulation, including
 - EN ISO 14971 Application of risk management to medical devices
 - EN IEC 62304 Medical device software - Software life cycle processes
- Requirements for interoperability
 - EN ISO 27269 International Patient Summary
 - EN ISO 17523 Requirements for electronic prescriptions
 - CEN ISO/TS 19293 Requirements for a record of dispense
 - EN ISO 12052 <reference to DICOM standards for medical imaging>
 - EN ISO 21860 Reference standards portfolio for clinical imaging
- Requirements for security
 - EN ISO 27799 Information security management in health using ISO/IEC 27002
 - CEN ISO/TS 14441 Security and privacy requirements of EHR systems
 - EN ISO 25237 Health Informatics - Pseudonymization

EN ISO 27269 International Patient Summary

- er baseret på to grundlæggende dimensioner/akser i forhold til *klinisk relevans*

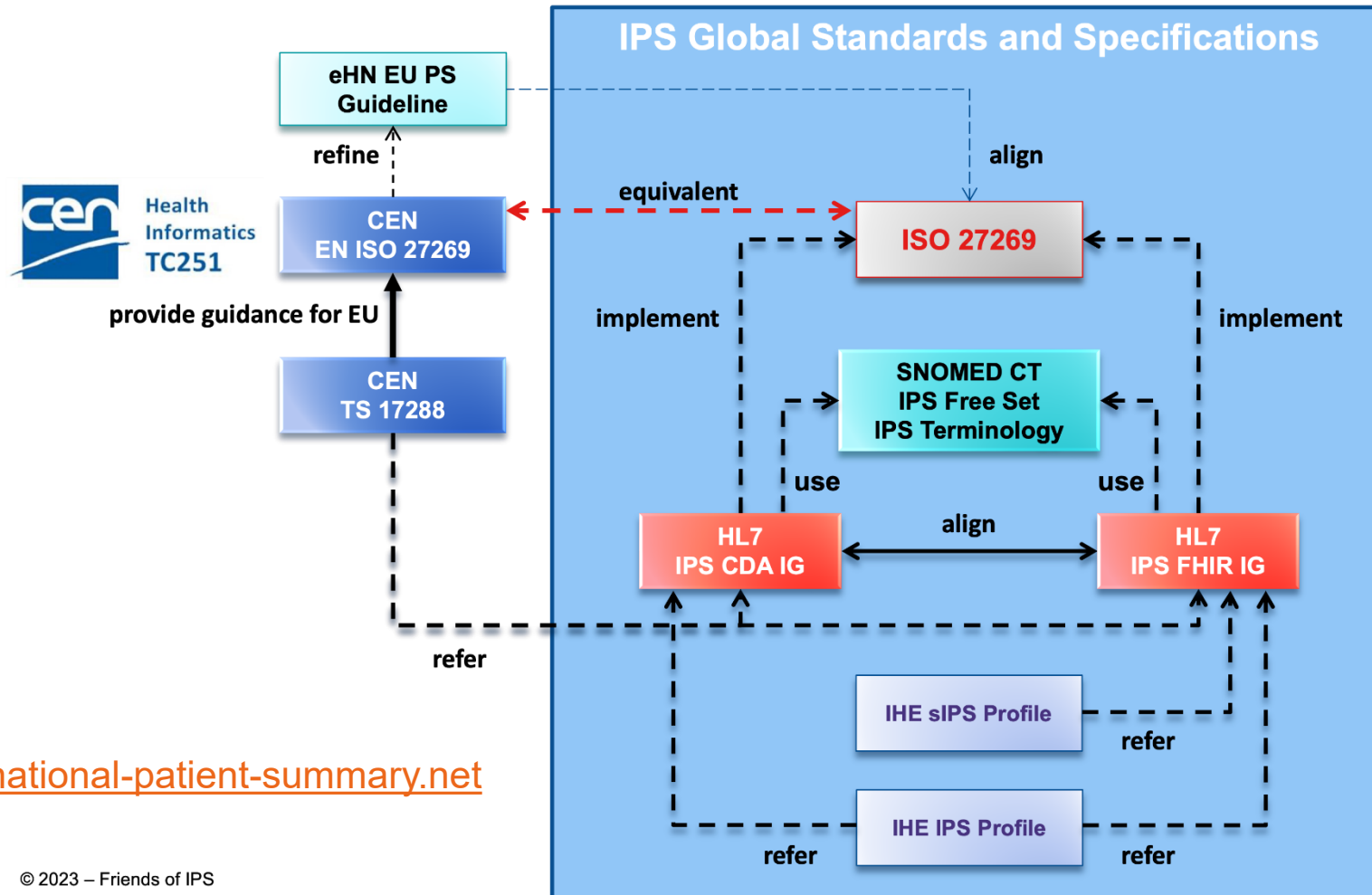
- I form af *egenskaber*, at være

- Minimalt
- Ikke udtømmende
- Speciale uafhængigt
- Uafhængigt af helbredstilstand

- I form af *principper*, om at være

- Implementerbar
- Globalt anvendelig
- Mulig at udvide
- Bæredygtig

IPS som et eksempel på SDO samarbejde



See also:

<https://international-patient-summary.net>

EHDS og EU-projekter

- EU-projekter har skullet levere grundlaget for de tekniske specifikationer, særligt
 - Xt-EHR – vedrørende primær anvendelse og EPJ
 - Stort fokus på dette projekt, herunder i relation til EEHRxF format samt indhold
 - Projektets leverancer har været i høring gennem det meste af 2025 og start 2026, som en af projektet defineret høring med udvalgte interessenter, herunder de nationale NCP/DHA
 - TEHDAS2 – vedrørende sekundær anvendelse
 - Projektets leverancer har været i offentlig høring 2025 og 2026
 - TEHDAS2 og sekundær anvendelse er lidt mindre i fokus på linje med sekundærsiden generelt i Danmark og en forventning om at Visionen for bedre brug af Sundhedsdata kommer til at løfte en større del heraf ift EHDS (med et vist ambitionsniveau)

Hovedindtrykkene af EHDS specifikationerne indtil nu

- Ift Patient Resume (1)
 - Dilemmaer, mellem en fælles europæisk standard som mulig fællesnævner, og ønsket om omfattende mængder af strukturerede data.
 - ISO 27269 International Patient Summary er mere overordnet, skåret ind til benet og giver klinisk værdi, EHDS går langt videre i detaljerigdom, uden helt at have et realistisk blik for hvad det kræver.
 - Compliance er lav (25%) set ift eksisterende implementeringer af PS, set under eet i forhold til hver af nationalstaternes efterlevelse.
 - Overordnet er rammerne ikke på plads.

Hovedindtrykkene af EHDS specifikationerne indtil nu

- Ift Patient Resume (2)
 - Aktuelle dybde af EHDS specifikationer kan ikke ses isoleret fra forskellige arbejdsgange, bedste praksis og guidelines, for ikke at nævne sprog.
 - Der mangler veldefinerede, udtømmende formelle beskrivelser af modeller og datasæt efter gængse standarder og principper til overblik og forståelse, især i forhold til muligheder, begrænsninger og antagelser.
 - Der er omfattende tavs/implicit viden, der er nødvendig for fuldt ud at forstå modellerne og deres implikationer, herunder med hensyn til bindinger til ICD10, potentielt ICD11, ORPHA-koder og SNOMED CT.
 - Få dataelementer er obligatoriske, men der er (alt for) mange, ikke altid klart afgrænsede i forhold til hinanden, samt klart beskrevne og definerede.

Hovedindtrykkene af Xt-EHR leverancerne indtil nu

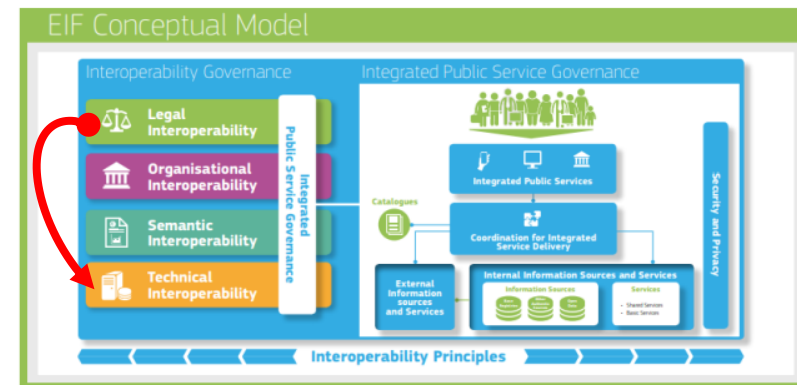
- Derudover ift Medicin Ordination/Udlevering, Udskrivningsrapporter (Discharge Reports), Overensstemmelses (Conformance) krav og EEHRxF metadata
 - Samme information og emner beskrives på forskellig vis i forskellige dele af leverancerne, på forskellige niveauer, med manglende alignment og komplethed
 - Der mangler definitioner ift aktører, roller og use cases, herunder hvor systemaktører er inkluderet, og ift datadelingsmønstre (push kontra pull)
 - Der mangler håndtering af oversættelse mellem de mange sprog i EU, herunder ift hvor, hvordan og hvem der har ansvaret
 - Hvor der peges på og anvendes (SDO) standarder som grundlag er det en sund tilgang, men der afspejles også et ekstremt højt ambitionsniveau med EHDS
 - Hvilket tillige stiller dramatisk øgede krav til medlemslandene, deres nationale infrastrukturer og digitale sundhedsmyndigheder i forhold til i dag.

Fra regionalt hold

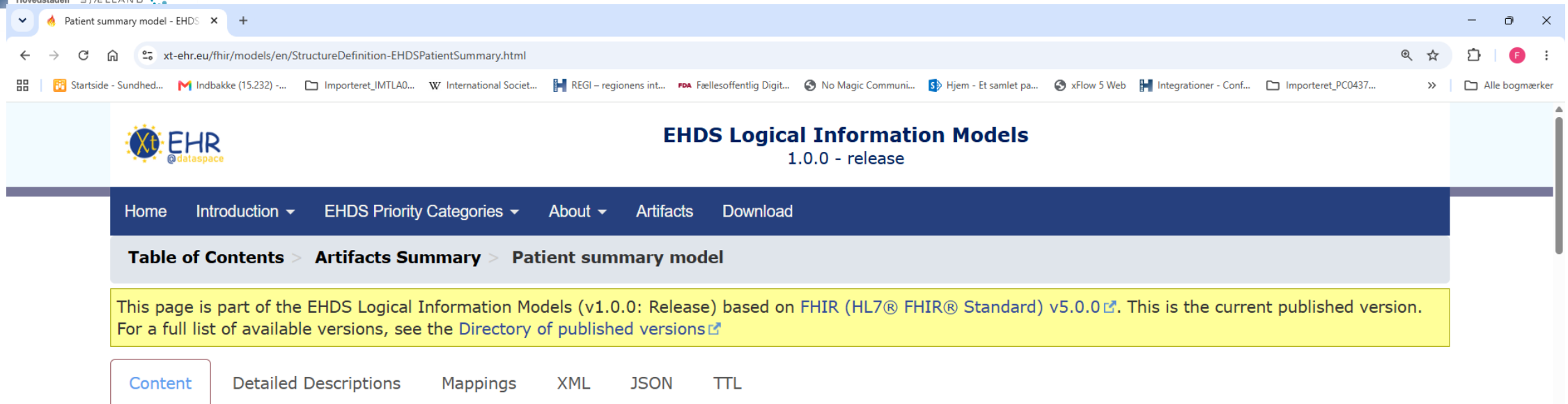
- Ønsker vi at konsolidere, formalisere og udvide eksisterende RSI EHDS-arbejdsgruppe og samarbejde med SDS/DSD, med 2-3 hovedspor
 1. Strategisk, på tværs og i sammenhæng med bl.a. Sundhedsreformen og andre nationale tiltag
 2. Interessevaretagende, gennem kommenteringer, involvering i EU-projekter og –arbejdsgrupper, ift. tekniske specifikationer og bidrag til nationale arkitektur målbilleder
 3. Analyser herunder fit-gap vedrørende vores systemlandskaber
- I relation til EU's EHDS komitologi-proces har vi ikke mindst været inde over
 - Artikel 15 (EEHRxF), og dertil hørende gennemførelsesretsakter
 - Med EHDS som enterprise arkitekturmæssigt noget udfordrende

FDA-reol

- og European Interoperability Framework (EIF)



	Konceptuel (Overbliksniveau)	Logisk (Designniveau)	Fysisk (Realiseringsniveau)
Styring	Styringsrammer	Fremgangsmåde	Relaliseringsforløb
Strategi	Vision og mål	Målearkitektur (resumé)	Løsningsarkitektur (resumé)
Jura	Juridiske rammer	Juridisk fortolkning	Juridisk praksis
Sikkerhed	Sikkerhedsstandard	Sikkerhedsmodeller og regler	Sikkerhedskontrol
Opgaver	Forretningsstruktur	Processer	Arbejdstilrettelæggelse
Information	Forretningsobjekter og begreber	Logiske datamodeller	Fysiske datamodeller
Applikation	Applikationslandskab og integrationsmønstre	Applikationslandskab og integrationer	Applikationsdesign og konfiguration
Infrastruktur	Infrastrukturmønstre	Infrastrukturlandskab	Infrastrukturkonfiguration



The screenshot shows a web browser displaying the 'EHDS Logical Information Models' website. The browser's address bar shows the URL 'xt-ehr.eu/fhir/models/en/StructureDefinition-EHDSPatientSummary.html'. The website has a dark blue header with the 'XtEHR @dataspace' logo and the title 'EHDS Logical Information Models 1.0.0 - release'. A navigation bar below the header contains links: Home, Introduction, EHDS Priority Categories, About, Artifacts, and Download. A breadcrumb trail reads 'Table of Contents > Artifacts Summary > Patient summary model'. A yellow box contains a notice: 'This page is part of the EHDS Logical Information Models (v1.0.0: Release) based on FHIR (HL7® FHIR® Standard) v5.0.0. This is the current published version. For a full list of available versions, see the Directory of published versions'. Below this, a tabbed interface shows 'Content' as the active tab, with other tabs for 'Detailed Descriptions', 'Mappings', 'XML', 'JSON', and 'TTL'.

18.1.1 Logical Model: Patient summary model

Official URL: http://www.xt-ehr.eu/fhir/models/StructureDefinition/EHDSPatientSummary	Version: 1.0.0
Computable Name: EHDSPatientSummary	

The model is a structured document designed to provide an overview of a patient's most important health information. The model aims to be compatible with the ISO International Patient Summary standard.

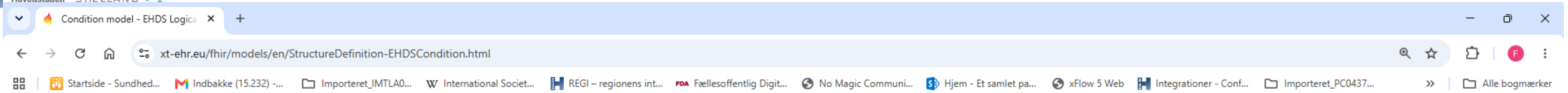
Patient summary consists of several sections of which some are suggested to be mandatory to support. For each mandatory section, implementers should as a minimum be able to produce a generated narrative text of the content, as well as certain structured elements. There are only few elements that are suggested as required to support at this point.

While the overall use cases for exchanging a full Patient Summary (PS) remain consistent—typically aiming to support patients access to its own data, transfer of data between systems and cross-border care (both emergency access, and continuity of care)—it is acknowledged that, in practice, implementers will need to support multiple variants of these use cases, depending on the context. In some cases, only a subset of the PS (e.g. just medications, allergies, or vaccinations) will be relevant or exchanged. As such, each section of the Patient Summary is described and handled independently, with clear guidance on both the narrative and structured

Browser tabs: Patient summary model - EHDS

URL: xt-ehr.eu/fhir/models/en/StructureDefinition-EHDSPatientSummary.html

header			
period	0..1	Period	Time period of information covered in the document
alerts	0..1	Base	Section: Alerts
generatedNarrative	0..1	string	Narrative, potentially formatted, content of the whole section.
medicalAlert	0..*	EHDSAlert	Description of medical alerts in textual format: any clinical information that is imperative to know so that the life or health of the patient does not come under threat.
note	0..1	string	Free text notes by the health professional
allergiesAndIntolerances	1..1	Base	Section: Allergies and intolerances
generatedNarrative	0..1	string	Narrative, potentially formatted, content of the whole section.
allergyIntolerance	0..*	EHDSAllergyIntolerance	List of structured allergies and intolerances
emptyReason	0..1	CodeableConcept	Use if no Allergies are listed
note	0..1	string	Free text notes by the health professional
problems	1..1	Base	Section: Medical problems
generatedNarrative	0..1	string	Narrative, potentially formatted, content of the whole section.
emptyReason	0..1	CodeableConcept	Use if no conditions are listed
problem	0..*	EHDSCondition	Health conditions affecting the health of the patient.
note	0..1	string	Free text notes by the health professional
medicationSummary	1..1	Base	Section: Medication summary
generatedNarrative	0..1	string	Narrative, potentially formatted, content of the whole section.
emptyReason	0..1	CodeableConcept	Use if no medicines are listed
medicationUse	0..*	EHDSMedicationUse	Medication treatment/prescription relevant for this patient summary. Typically, medications whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not.
note	0..1	string	Free text notes by the health professional
medicalDevicesAndImplants	1..1	Base	Section: Medical devices and implants
generatedNarrative	0..1	string	Narrative, potentially formatted, content of the whole section.
emptyReason	0..1	CodeableConcept	Use if no conditions are listed
deviceUse	0..*	EHDSDeviceUse	Describes the patient's implanted and external medical devices and equipment that their health status depends on. Includes devices (such as cardiac pacemakers, implantable defibrillator, prosthesis, ferromagnetic bone implants etc.) that are important to know by the HP.
note	0..1	string	Free text notes by the health professional



18.17.1.1 Formal Views of Profile Content

Description Differentials, Snapshots, and other representations [↗](#).

Differential Table

Snapshot Table

Statistics/References

All

Name	Flags	Card.	Type	Description & Constraints	Filter:
 EHDSCondition		0..*	EHDSDataSet	Condition model	
Elements defined in Ancestors:header					
 header					
 author[x]		0..*	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	The author of the condition information.	
 status		1..1	CodeableConcept	Status of the condition/problem (e.g. active, resolved, inactive, etc)	
 problem		1..1	CodeableConcept	Code identifying the condition, problem or diagnosis	
 onsetDate		0..1	dateTime	Onset date of a problem/condition	
 endDate		0..1	dateTime	The date or estimated date that the condition resolved or went into remission	
 category		0..*	CodeableConcept	Category or categories of the problem (e.g. POA - present on admission, HAC - hospital aquired condition, and other categorisations).	
 resolutionCircumstances		0..1	string	Describes the reason for which the status of the problem changed from current to inactive (e.g. surgical procedure, medical treatment, etc.).	
 severity		0..1	CodeableConcept	A subjective assessment of the severity of the condition as evaluated by the clinician.	
 bodySite		0..*	EHDSBodyStructure	The anatomical location including laterality where this condition manifests itself.	
 stage		0..*	CodeableConcept	Stage/grade usually assessed formally using a specific staging/grading system. Multiple assessment systems could be used.	
 diagnosisAssertionStatus		0..1	CodeableConcept	Assertion about the certainty associated with a diagnosis. Diagnostic and/or clinical evidence of condition.	

Browser tabs: Patient summary model - EHDS

URL: xt-ehr.eu/fhir/models/en/StructureDefinition-EHDSPatientSummary.html

generatedNarrative	0..1	string	Narrative, potentially formatted, content of the whole section.
observation	0..*	EHDSObservation	Social history observations related to health
note	0..1	string	Free text notes by the health professional
pregnancyHistory	0..1	Base	Section: Pregnancy history
generatedNarrative	0..1	string	Narrative, potentially formatted, content of the whole section.
currentPregnancyStatus	0..1	EHDSCurrentPregnancy	Current pregnancy status
previousPregnancies	0..*	EHDSPregnancyHistory	History of previous pregnancies
note	0..1	string	Free text notes by the health professional
travelHistory	0..1	Base	Section: Travel history
generatedNarrative	0..1	string	Narrative, potentially formatted, content of the whole section.
travelHistory	0..*	EHDSTravelHistory	Travel history for one country
note	0..1	string	Free text notes by the health professional
patientStory	0..1	Base	Section: Patient story
note	0..1	string	Free text notes by the health professional
advanceDirectives	0..1	Base	Section: Advance Directives
generatedNarrative	0..1	string	Narrative, potentially formatted, content of the whole section.
advanceDirective	0..*	EHDSAdvanceDirective	Provision for healthcare decisions if, in the future, a person is unable to make those decisions
note	0..1	string	Free text notes by the health professional
observationResults	0..1	Base	Section: Observation results
generatedNarrative	0..1	string	Narrative, potentially formatted, content of the whole section.
result	0..*	EHDSObservation	Observation results pertaining to the subject of care's health condition and which might have impact on future treatments
note	0..1	string	Free text notes by the health professional
carePlans	0..1	Base	Section: Care plans
generatedNarrative	0..1	string	Narrative, potentially formatted, content of the whole section.
carePlan	0..*	EHDSCarePlan	Describes the intention of how one or more practitioners intend to deliver care for a particular patient for a period of time, possibly limited to care for a specific condition or set of conditions.
note	0..1	string	Free text notes by the health professional

component	0..*	Base	Component in case the observation consists of multiple sub-observations (e.g. blood pressure).
type	1..1	CodeableConcept	Code representing the observation using the agreed code systems. Binding Description: (preferred): LOINC, SNOMED CT
originalName	0..1	string	Original (user-friendly) name of the observation as used in the local laboratory or clinical system.
result	1..1	Base	Result of the observation including text, numeric, coded, and other types of results of the measurement and measurement uncertainty. Content of the observation result will vary according to the type of the observation.
value[x]	0..1		Observation result value according to the type of observation. Model covers only most frequently used data types but other data types can be used as well. Text result value should be used only if coded result value is not expected otherwise use valueCodeableConcept.text. For Quantity, Range and Ratio, result units of the measurement should be provided. Binding Description: (preferred): UCUM for units, SNOMED CT for coded results
valueString		string	
valueQuantity		Quantity	
valueRange		Range	
valueRatio		Ratio	
valueCodeableConcept		CodeableConcept	
uncertainty	0..1	Base	Measurement uncertainty type and interval if needed.
value	1..1	decimal	The numerical value of the measurement uncertainty.
type	0..1	Coding	Probability Distribution Type for uncertainty Binding Description: (preferred): HL7 ProbabilityDistributionType
dataAbsentReason	0..1	CodeableConcept	Provides a reason why the expected value in the element component.value[x] is missing. Binding Description: (preferred): HL7 Data absent reason
referenceRange	0..*	Base	Reference range, multiple reference ranges of different types could be provided. Provides guide for interpretation of the result.
low	0..1	Quantity	Low limit of the reference range. Binding Description: (preferred): UCUM for units
high	0..1	Quantity	High limit of the reference range. Binding Description: (preferred): UCUM for units
normalValue	0..1	CodeableConcept	Normal value, if relevant for the reference range. Binding Description: (preferred): SNOMED CT
type	0..1	CodeableConcept	Type of reference range. Binding Description: (preferred): HL7 Observation Reference Range Meaning Codes
appliesTo	0..*	CodeableConcept	Codes to indicate the target population this reference range applies to. Binding Description: (preferred): SNOMED CT, HL7 v3-Race
age	0..1	Range	Age range to which this reference range applies if applicable. Binding Description: (preferred): UCUM for units
text	0..1	string	Text based reference range in an observation.
interpretation	0..*	CodeableConcept	Information about reference intervals and result interpretation. Binding Description: (preferred): SNOMED CT, HL7 ObservationInterpretation
derivedFrom[x]	0..*		Reference to the related resource from which the observation has been made. For example, a calculated anion gap or a fetal measurement based on an ultrasound image.
derivedFromEHDSObservation		EHDSObservation	
derivedFromEHDSLaboratoryObservation		EHDSLaboratoryObservation	
derivedFromEHDSImagingStudy		EHDSImagingStudy	
hasMember[x]	0..*		This observation is a group observation (e.g. a battery, a panel of tests, a set of vital sign measurements) that includes the target as a member of the group.
hasMemberEHDSLaboratoryObservation		EHDSLaboratoryObservation	
hasMemberEHDSObservation		EHDSObservation	

- Modelmæssig gentagelse og redundans
- Ubegrænset indlejring
- Samme oplysninger kan placeres flere steder

Dilemma, det nationale kontra det fælleseuropæiske

- Mange nationale udgaver af datasæt i relation til EHDS eksisterer allerede i medlemslandene (fx fra EU projekter) som patient resumeer, medicin ordinationer/udleveringer, udskrivningsbreve
- Hvad er formålet med EHDS, udover det helt overordnede som indre marked for sundheds-ydelser, indre marked for sundheds-it systemer, europæisk dataøkonomi, vidtgående rettigheder for borgerne mht dataportabilitet og selvbestemmelse - handler det om at få mest muligt ud af EHDS nationalt i medlemslandene eller på tværs af disse?
- EHDS handler om patient resumeer (som ISO 27269), men også EPJ-ekstrakter
 - Hvor meget vil reelt kunne bruges særligt på tværs af medlemslandene?
 - Klinikere kræver normalt af data, at kontekst er kendt, og at man kan stole på datas præcision i forhold hertil
 - Er det godt nok, med "bedste klinikers bedste gæt" ?

Hvordan kommer vi videre, i forhold til EU

- Tidligere forslag fra en gruppe af lande i Xt-EHR om at konsolidere på en mindre omfattende, komplet logisk model med færre men obligatoriske dataelementer
- Forslag fra EHTEL (European Health Telematics Association) om flere faser, startende med de egentlige EPJ-systemer, og videreudvikling/vedligeholdelse af EEHRxF involverende bl.a. SDO'er under struktureret governance og processer
- Kommentarer fra regionerne som
 - Brug for mere metode, der definerer hvad der skal standardiseres på højere logisk, mindre detaljeret niveau, og en faseopdelt tilgang startende med mindre dataområder gradvist øgende bredde og dybde fx med udgangspunkt i ISO 27269 eller et subset, med mere realistisk ambitionsniveau og roadmap
 - Brug for udvikling af en logisk datamodel på højt niveau i UML som en afgørende forudsætning for interoperabilitet - en teknologiuaafhængig model der ligger tættere på forretningen, kvalitetssikret ift forretningen samt semantisk og teknisk, herunder med hensyn til konsistens, integritet, entydighed osv.

Hvordan kommer vi videre, i Danmark

- EHDS skal under alle omstændigheder også omsættes og udmøntes til danske forhold, herunder mhp. at give værdi ift. investering
- Der er store overlap og potentiale for synergi ift hvad man vil opnå, nationalt og europæisk, med deling af data, mellem parterne og på tværs
- Sundhedsreformen og EHDS bør tænkes sammen, i relation til nødvendig modernisering af nationale standarder, arkitektur og infrastruktur
 - Herunder vedr. National infrastruktur til deling af sundhedsdata (Dataplatformen)
- EHDS og tidens generiske snitflader lægger op til skifte i datadelingsparadigmer
 - Fra push til pull, hentning ved kilden, med mindre dansk-specifikke snitflader
 - Men også baseret på push i en overgangsfase (transition)
 - EHDS og Sundhedsreformen vil stille store krav både nationalt og lokalt
- Nationale målbilleder, målarkitekturer og roadmaps