RWE4Decisions REAL WORLD EVIDENCE

Public Webinar

HTA/Payer Collaboration in the Nordics: *The Role of Real-World Evidence*

On Zoom

23 October 2024, 15:00-16:30 CEST

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RWE4Decisions

HTA/Payer-led, multi-stakeholder Learning Network

RWE4Decisions brings together experts from all stakeholder groups to engage in dialogues that consider how fit-for-purpose RWE can be generated over the life cycle of **highly innovative medicines** through:

- horizon scanning systems that identify medicines which are most likely to need RWE
- identifying what RWE is needed to inform HTA/Payer decisions
- clarifying how RWE is generated by HTDs and will be assessed by HTA and used by Payers/decision-makers
- aligning planning and execution of effective Post Launch Evidence Generation (PLEG) studies.

RWE4Decisions REAL WORLD EVIDENCE 2024 STEERING GROUP

HTA bodies / Payers

Jo De Cock

Senior Adviser, **INAMI-RIZIV**

Diane Kleinermans

President. of Drug Reimbursement Commission, **INAMI-RIZIV**

Niklas Hedberg

Chief Pharmacist, **TLV**

Piia Rannanheimo

Chief Specialist, **Fimea**

Cláudia Furtado

Head HTA, P&R Div. and Information & Strategic Planning, **INFARMED**

Laurie Lambert

Special Projects Adviser, **CADTH**

National Policy-makers

Carlos M. Saborido

Adviser, **Spanish Ministry of Health**

International Org.

Eric Sutherland

Senior Health Economist, **OECD**

Industry

EUCOPE

AstraZeneca

Boehringer Ingelheim

GILEAD

MSD

NOVARTIS

Pfizer

Roche

Takeda

Patient Representatives

Chris Sotirelis

EURORDIS RARE DISEASES EUROPE

Patient Advocate for **Thalassemia**

Insurer

Hans-Georg Eichler

Consulting physician, **Austrian Social Insurance Inst.**

Clinician

Matti Aapro

Director, **Genolier Cancer Centre**

Analytics Expert

Ashley Jaksa

Market Access Scientific Strategy Lead, **Aetion, US**

Academia

Entela Xoxi

Pharmacologist, **Uni. Cattolica Sacro Cuore**

Facilitators

FIPRA International

Karen Facey, Senior Adviser (HTA)

François Meyer, Special Adviser (HTA)

Secretariat provided by FIPRA funded by EUCOPE and member companies

Housekeeping

Today's webinar is scheduled for **1.5 hours**

This meeting will be **recorded** and made available at *www.rwe4decisions.com*

Please **use the Q&A function** to ask a question or make a comment.
You can **upvote** other participant's comments

When asking a question, please **rename yourself** on Zoom to show name and affiliation

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ALEXANDER NATZ

Secretary-General, European Confederation of Pharmaceutical Entrepreneurs

TOVE HOLM-LARSEN

Chief Executive Officer, Silvi.ai;
Professor, Ghent University

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KEYNOTE SPEAKER

EHM ANDERSSON GALIJATOVIC

Medical Assessor, Chief Consultant,
Danish Medicines Council

Joint Nordic HTA-Bodies, JNHB

RWE4Decisions webinar 23 October 2024

Ehm Andersson Galijatovic, DMC

JNHB
Joint Nordic HTA-Bodies

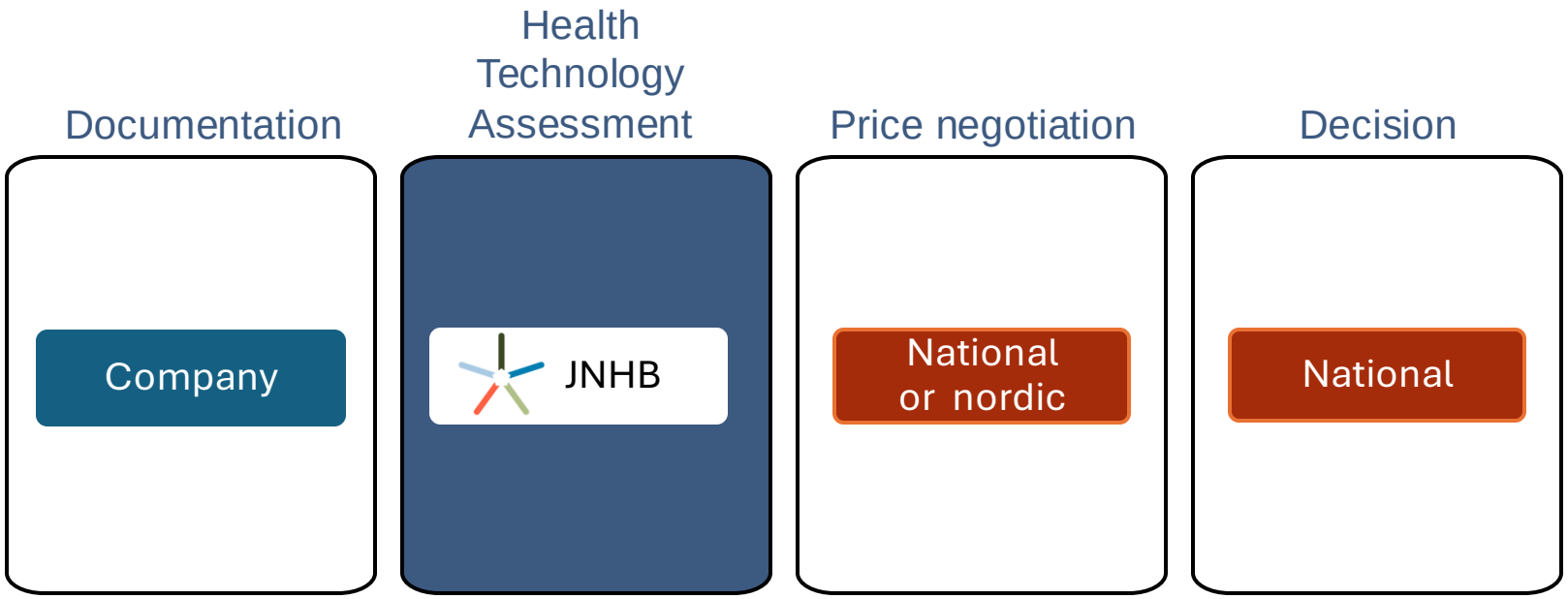
FINOSE becomes Joint Nordic HTA-Bodies

Stockholm April 2024

- **FINOSE initiated as bottom-up initiative from the FI, NO, SE authorities**
- **Launched as Joint Nordic HTA-bodies June 2024, now includes DK, FI, IS, NO, SE**

JNHB
Joint Nordic HTA-Bodies

JNHB is a collaboration on Health Technology Assessments



Schematic overview of the steps from documentation to decision

JNHB
Joint Nordic HTA-Bodies

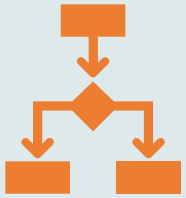
JNHB

Best practice from the Nordic HTA bodies

Sharing of resources and knowledge – high quality in assessments

Less divergence in HTA methodologies and evidence requirements

Supports timely and equal access for Nordic patients



Adaption to the JCA-process in the upcoming HTA regulation

Supports joint Nordic price negotiations

A flexible system beneficial for both companies and HTA bodies

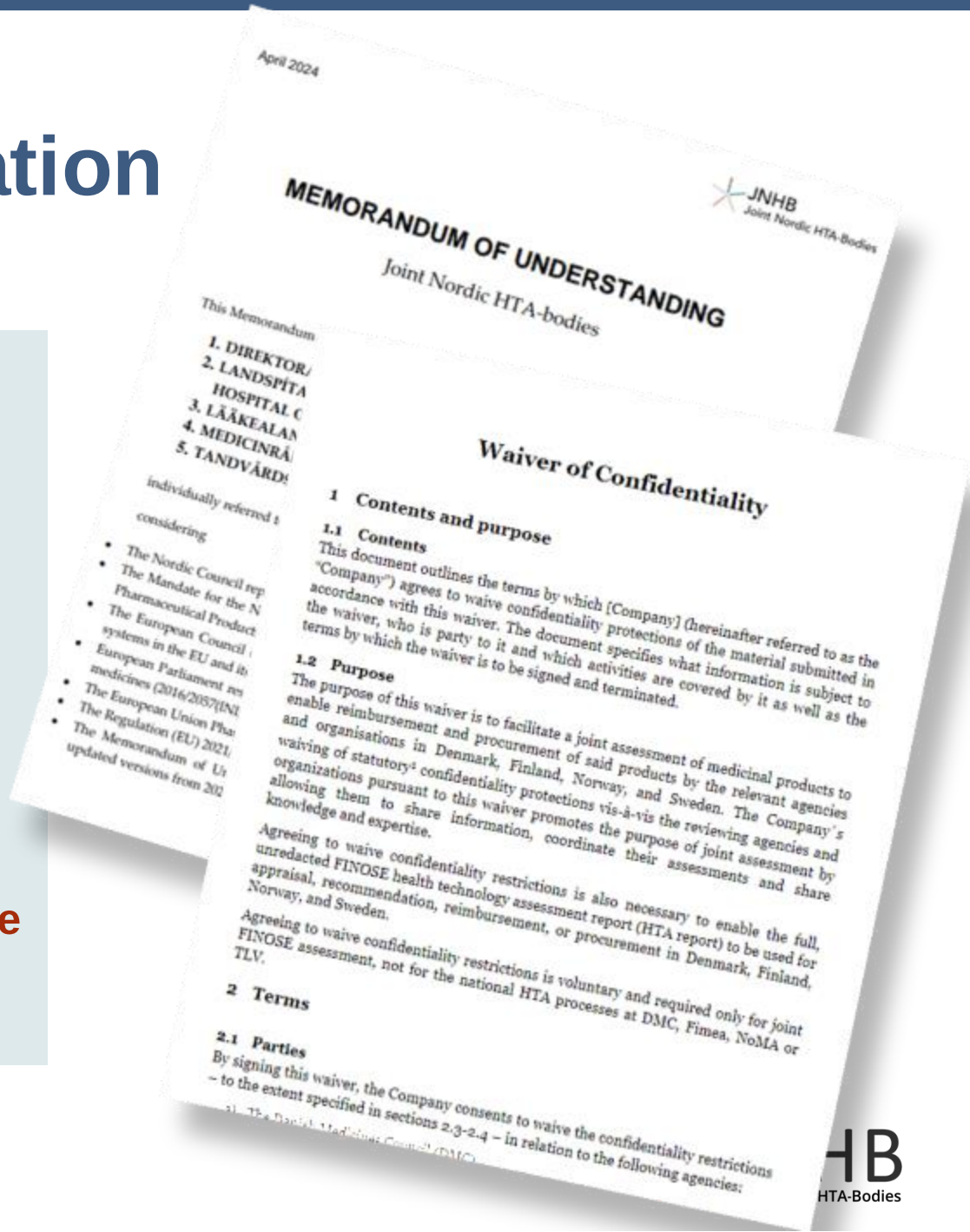
Documents in the collaboration

Memorandum of Understanding

- The basis for the JNHB collaboration
- Defines scope and legal basis

Waiver of Confidentiality

- Allows the HTA agencies to share confidential information during the assessment
- Allows the price negotiating parties to receive the unredacted HTA reports


April 2024

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MEMORANDUM OF UNDERSTANDING

Joint Nordic HTA-bodies

Waiver of Confidentiality

1 Contents and purpose

1.1 Contents

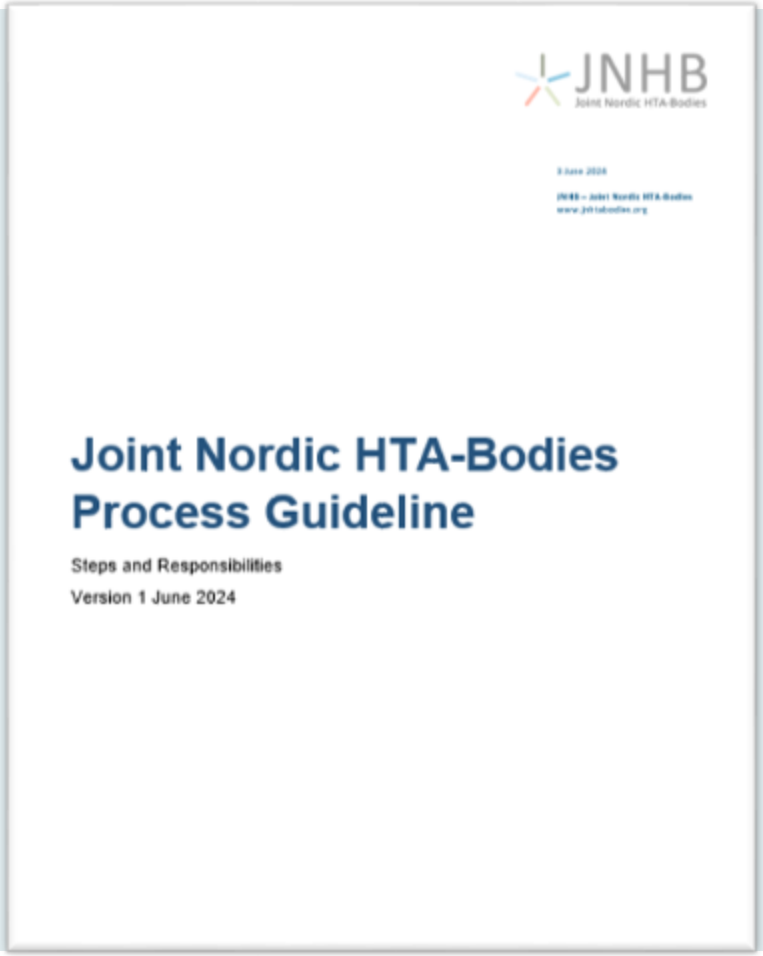
1.2 Purpose

2 Terms

2.1 Parties

JNHB Process Guideline

- Process steps
- Timelines of the assessment
- Roles and responsibilities



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Q&A section

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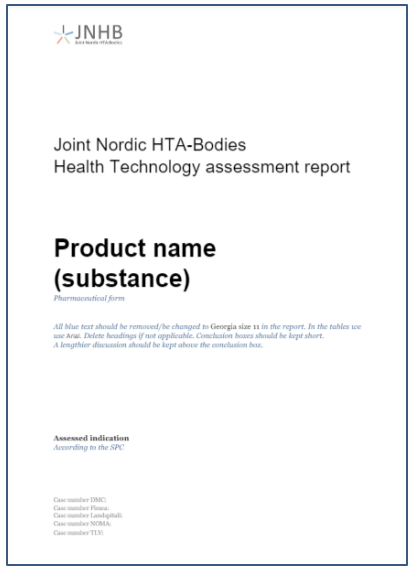
Roles and responsibilities

Assessor
- Contact
- Coordination
- Medical/HE assessor

Co-assessor
- Medical/HE assessor


JNHB

Joint Nordic HTA-Bodies
Health Technology assessment report

Product name (substance)

Pharmaceutical form

All blue text should be removed/be changed to Georgia size 11 *in the report. In the tables we use* Arial. *Delete headings if not applicable. Conclusion boxes should be kept short. A lengthier discussion should be kept above the conclusion box.*

Assessed indication
According to the SPC

Case number DMC:
Case number Fimea:
Case number Landspitali:
Case number NOMA:
Case number TLV:

Reviewers

Observers

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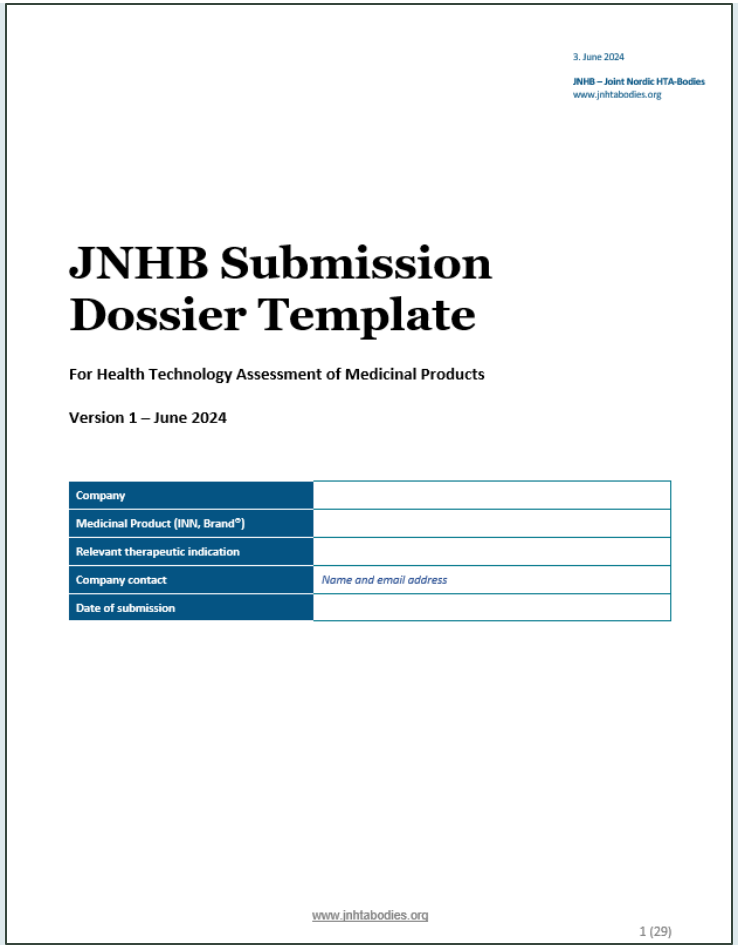
JNHB Submission Dossier Template



3. June 2024

JNHB – Joint Nordic HTA-Bodies
www.jnhtabodies.org

JNHB Submission Dossier Template

For Health Technology Assessment of Medicinal Products

Version 1 – June 2024

Company	
Medicinal Product (INN, Brand®)	
Relevant therapeutic indication	
Company contact	*Name and email address*
Date of submission	

www.jnhtabodies.org

1 (29)

- Aims to describe what information is needed in a dossier for a joint Nordic HTA
- Support HTD in the submission
- Guidance on how to include national requirements in the HE-model

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Q&A section

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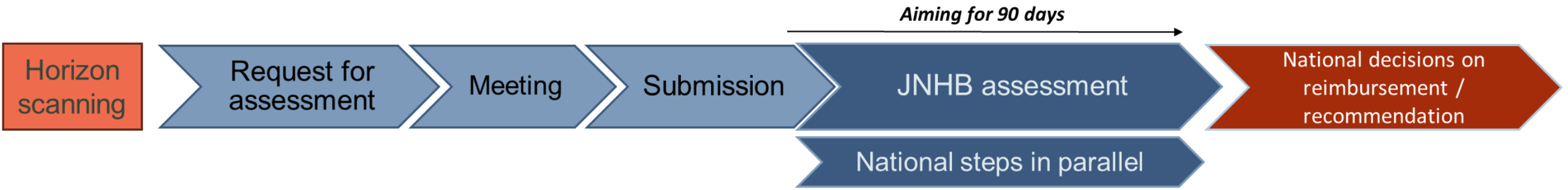
Submission template

- Same health economic model structure for all countries
- The submitted model should be flexible and adjustable to all countries
- The model should allow an easy and unambiguous way to get results for each country
- The country-specific input could preferably be included in the form of drop-down menus to allow the assessment team to switch between the settings in the model
- The country-specific input are described in more detail in the submission dossier template

The JNHB process – Joint HTA and national decision making



Information from Nordic HS initiatives

HTD describes Nordic treatment landscape and signs Waiver of Confidentiality.

For suitable products, the HTD is invited to a meeting with JNHB.

The HTD submits one dossier and the HE-model.

Relative effectiveness and health economics assessed. Joint report is written in English.

Price negotiations on national or Nordic level can take place based on the joint report.

The joint report is used to support decisions on reimbursement on national level.

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KEYNOTE SPEAKER

MARIA ERIKSSON

Medical Assessor, Dental and Pharmaceutical Benefits Agency (TLV)

From FINOSE to JNHB

- National, Nordic and HTAR perspective

RWE4Decisions webinar 23 October 2024

Maria Eriksson, TLV

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TLV is a governmental agency under the Ministry of Health and Social Affairs

Amongst other things TLV is assigned to conduct health economic assessments, HTA

- TLV conducts HTA and decide on the pricing and reimbursement of out-patient products
- TLV conduct HTA for products for in-hospital use
- TLV assesses both medicinal products and medical devices

In English - Tandvårds- och läkemedelsförmånsverket TLV

Different process for in- and outpatient drugs in SE

Out-patient products

”Three-party negotiations”

Companies apply to TLV for reimbursement

HTA conducted by TLV

The pharmaceutical benefits board (TLV) decides on price and reimbursement

New medicinal products and medical devices

In-hospital products

Regions request HTA from TLV

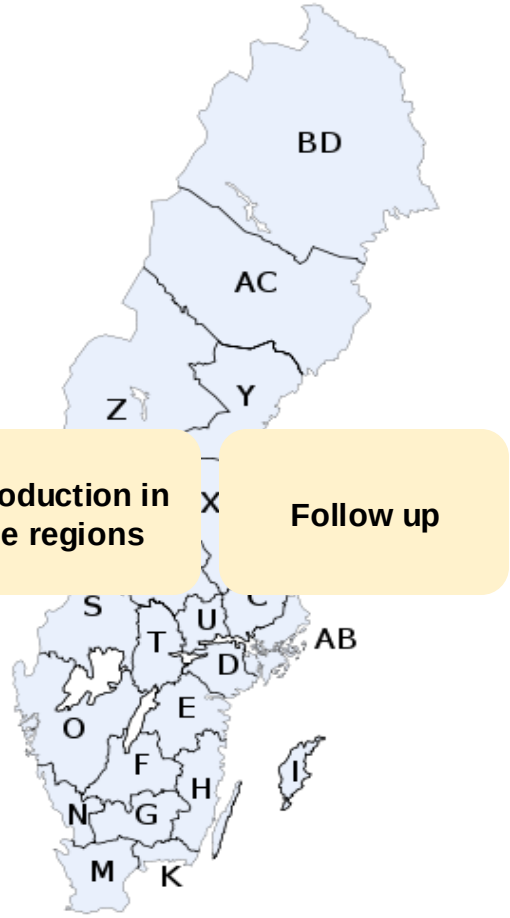
HTA conducted by TLV

The regions issue recommendations for use

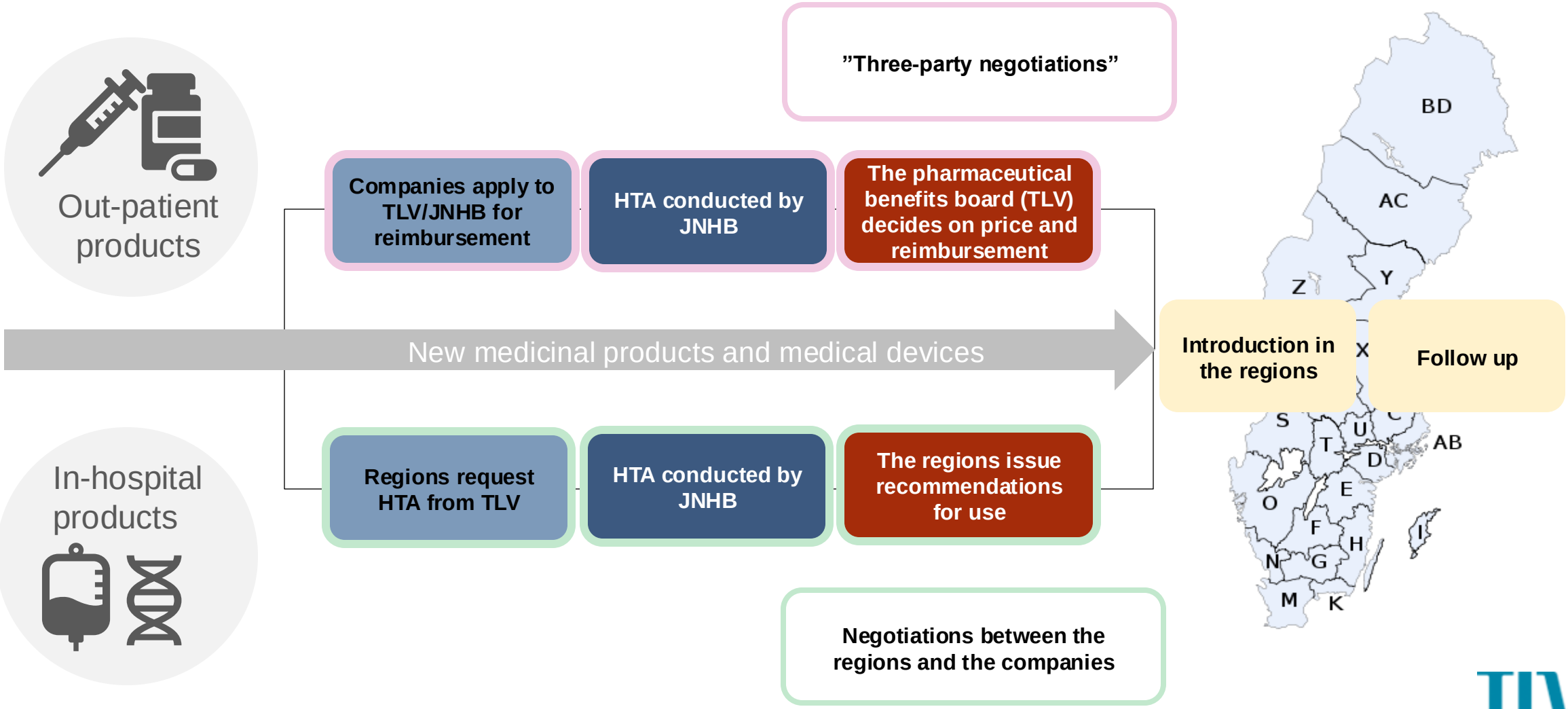
Negotiations between the regions and the companies

Introduction in the regions

Follow up



With FINOSE/JNHB the HTA step is conducted at Nordic level & replaces the national HTA



National steps for a joint Nordic HTA

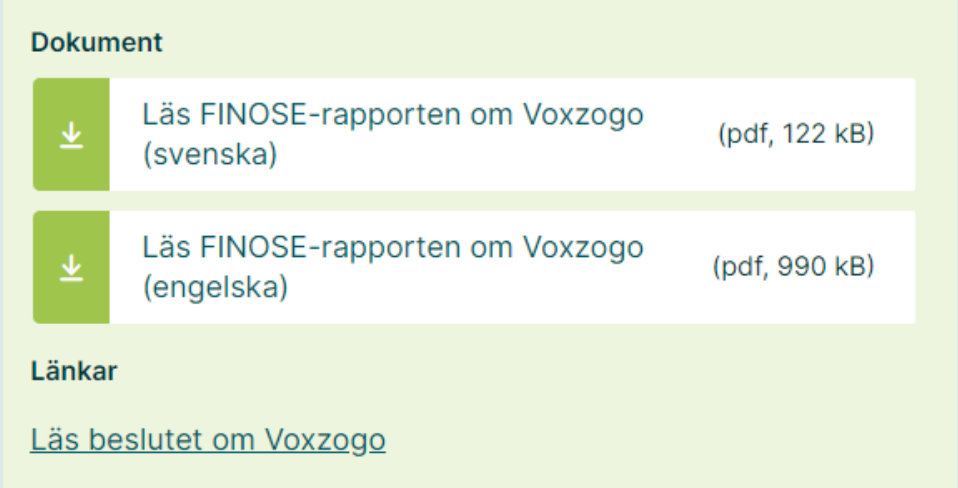
National appendix in SE may include:

- Summary in national language
- Currency conversion to SEK
- Factors specific for SE, if relevant
- Calculations related to disease severity

- Result of national price negotiations
- For out-patient products decision document written in Swedish

Aim to finalize national appendices simultaneously with the JNHB-report

Published at TLV.se



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Main differences between FINOSE and JNHB

- Five countries included
- Supporting documents developed
- Clarification of roles and responsibilities
- Clarification of time-lines, review periods etc
- Better equipped to reach 90-days goal
- Joint webpage and mail address

- Continuous development of the collaboration

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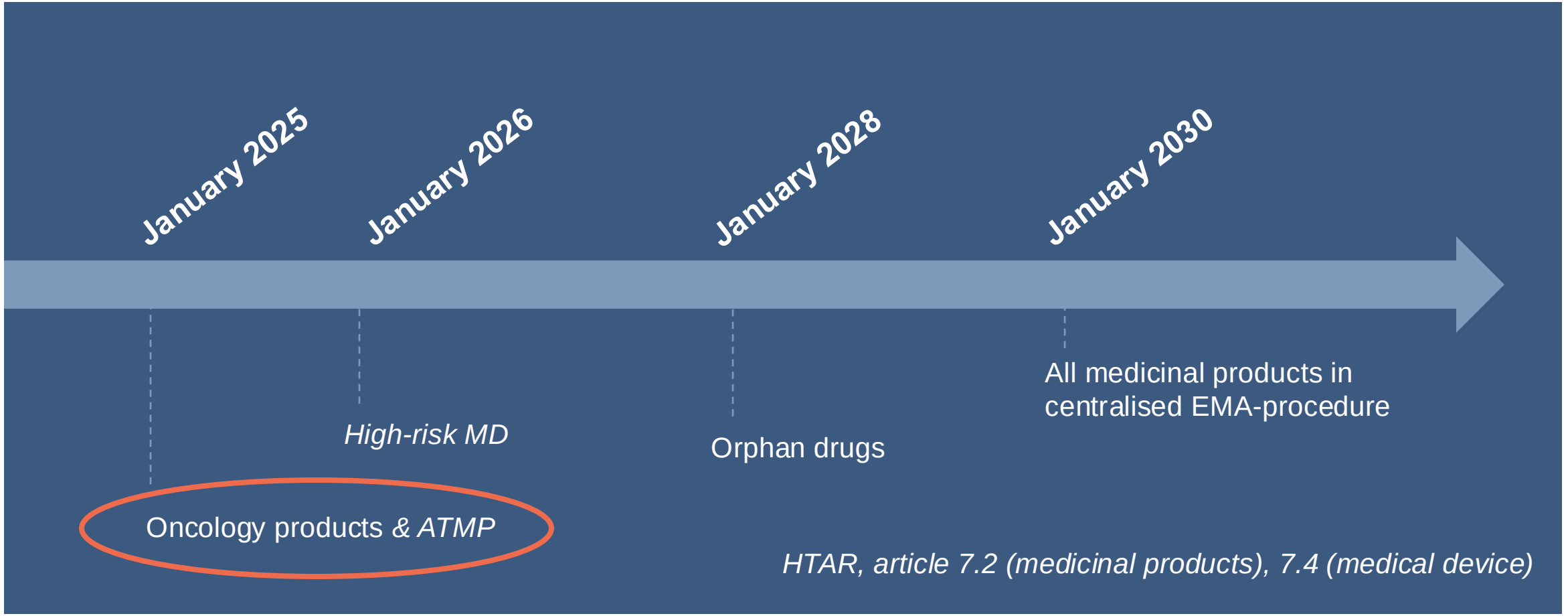
The HTA regulation will be implemented step-wise starting from January 2025



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Structure of HTA-R work at EU-level

EUROPEAN COMMISSION

(DG-SANTE, HTA-secretariate)

COORDINATION GROUP (CG)

Chair: Roisin Adams (IE)
Co-chair (medicinal products): Niklas Hedberg (SE), Co-chair (medical device): Marco Marchetti (IT)

COMMITTEE ON HTA

(DG-SANTE, Member state representatives)

MPG

Subgroup for Development of methodological and procedural guidance

Chair/Co-chair: DE/PT

JCA

Subgroup for Joint Clinical Assessments

Chair/Co-chair: FR/NL

JSC

Subgroup for Joint Scientific Consultations

Chair/Co-chair: DE/ES

EHT

Subgroup for Identification of Emerging Health Technologies

Chair/Co-chair: DK/IT

JNHB
Joint Nordic HTA-Bodies

Adaptions of JNHB to the HTAR

- Several JNHB members have had prominent roles in EUnetHTA (JA1-JA3) and the EUnetHTA21 tender period.
- JNHB members are represented in the Coordination Group, the subgroups and the committee on HTA and actively involved in the HTAR implementation.
- In line with the intention expressed in the HTAR, JNHB will consider JCA reports as valid documents for JNHB assessments.

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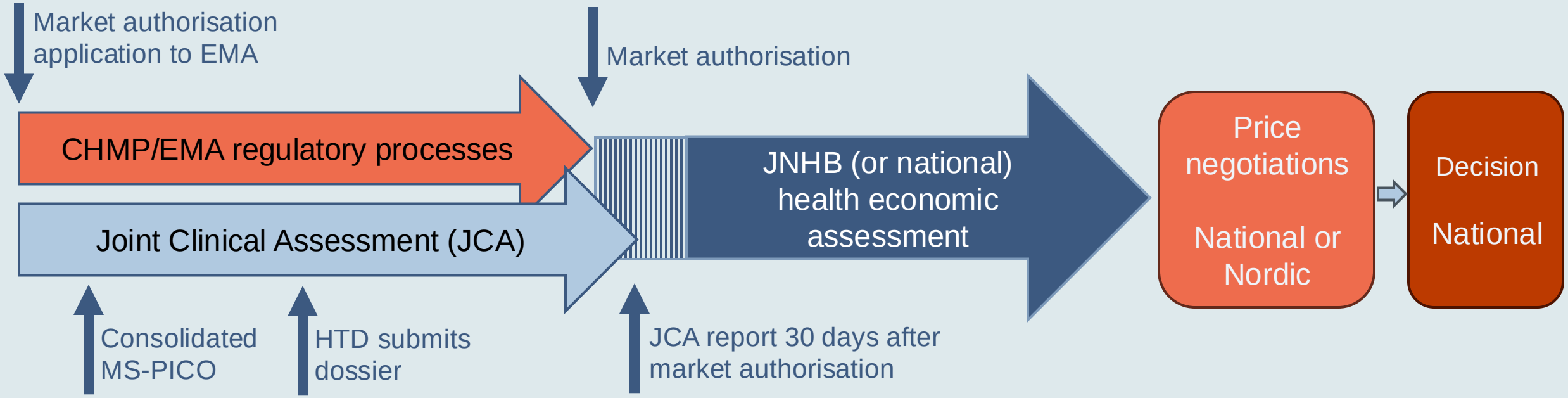
Adaptions of JNHB to HTA regulation



- With JCA-process, the PICO known at early stage.
- Facilitates planning for health economic assessment through JNHB.
- Cancer products and ATMPs concerned from January 2025.

Not drawn to scale

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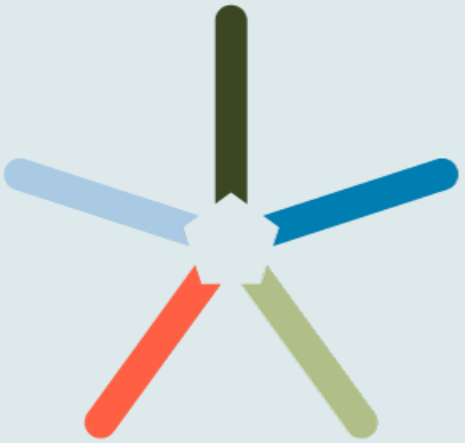
JNHB going forward

- Goals for JNHB
  - Knowledge sharing and high quality in assessments
  - Increase the number of joint assessments
  - Decrease divergence in methodology and evidence requirements
  - Improve JNHB process and increase transparency of joint work
  - Adapt to EU-HTA

Questions & More Information



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KIMMO PORKKA

Professor of personalised cancer medicine /
Chief Physician, University of Helsinki

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HTA/Payer National Collaborative Initiatives – The Role of Real-World Evidence

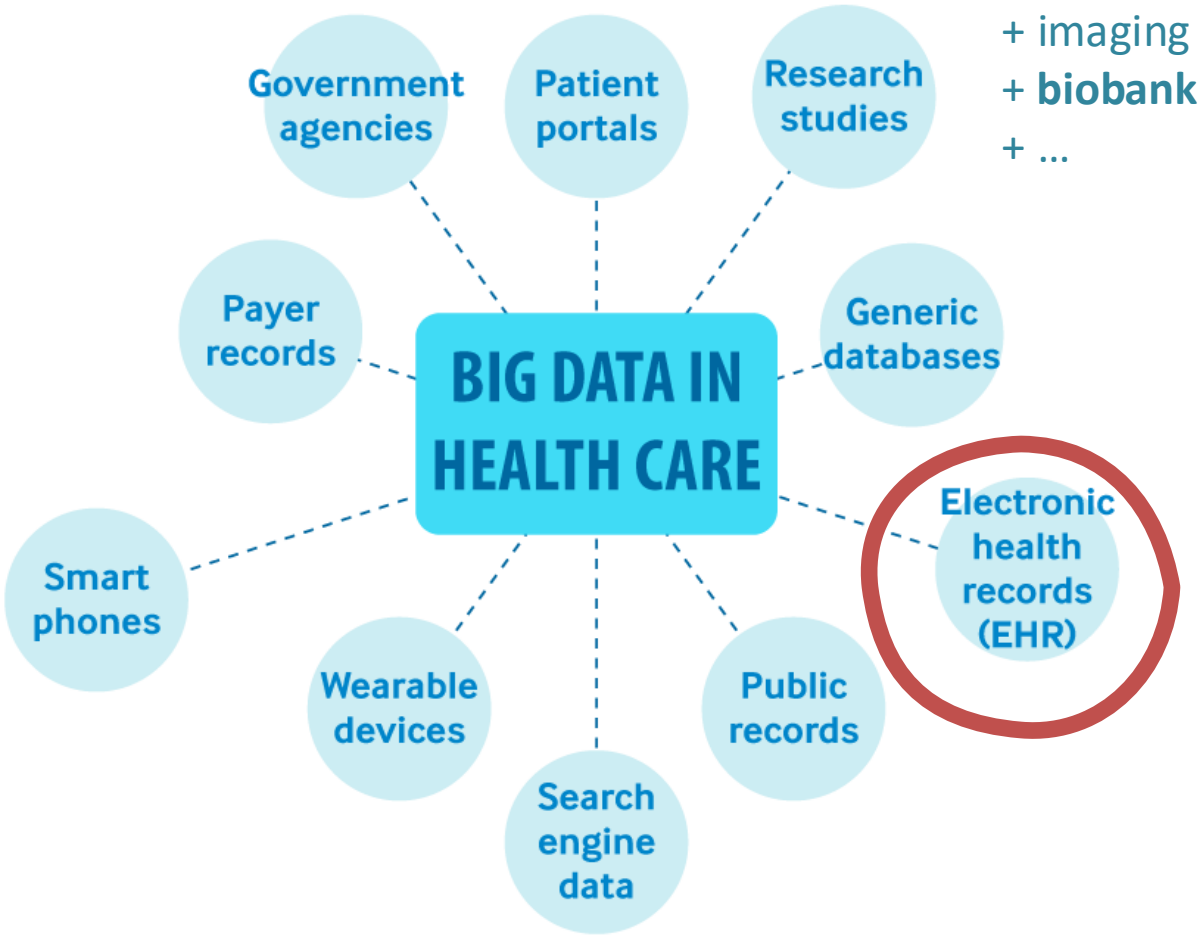
Kimmo Porkka

Professor of Personalized Cancer Medicine
iCAN Digital Precision Cancer Medicine Flagship, University of Helsinki

Chief physician, Department of Hematology
Helsinki University Hospital Comprehensive Cancer Center

Some sources of real-world data (RWD) in health care

+ global tumor profiling data
+ imaging data
+ **biobank data**
+ …



Real-world data (RWD)

Some use cases for RWD and generating RWE

- Clinical, regulatory: **Biomarker discovery and validation**
  Matching right patients with right drugs and treatments
  Hypothesis generation
  Trial feasibility assessment

- Regulatory: **Common standard arm (HR <0.7)**, RWD-generated, for drug trials
  Optimizing resources, statistical power
  Could be synthetic

- Clinical: learning decision support systems (**CDS**)

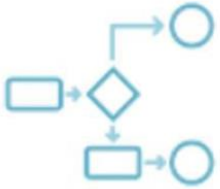
  Clinical: **Digital phenotyping**

- Regulatory: **HTA** – health technology assessment
  PLEG – post-licensing evidence generation

What is needed to facilitate RWE generation at scale?

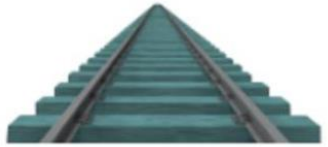
Data interoperability

<u>Data harmonization</u>
Common data model



Standardised analytics

Community supported
Open source
Accessible analytics/reporting



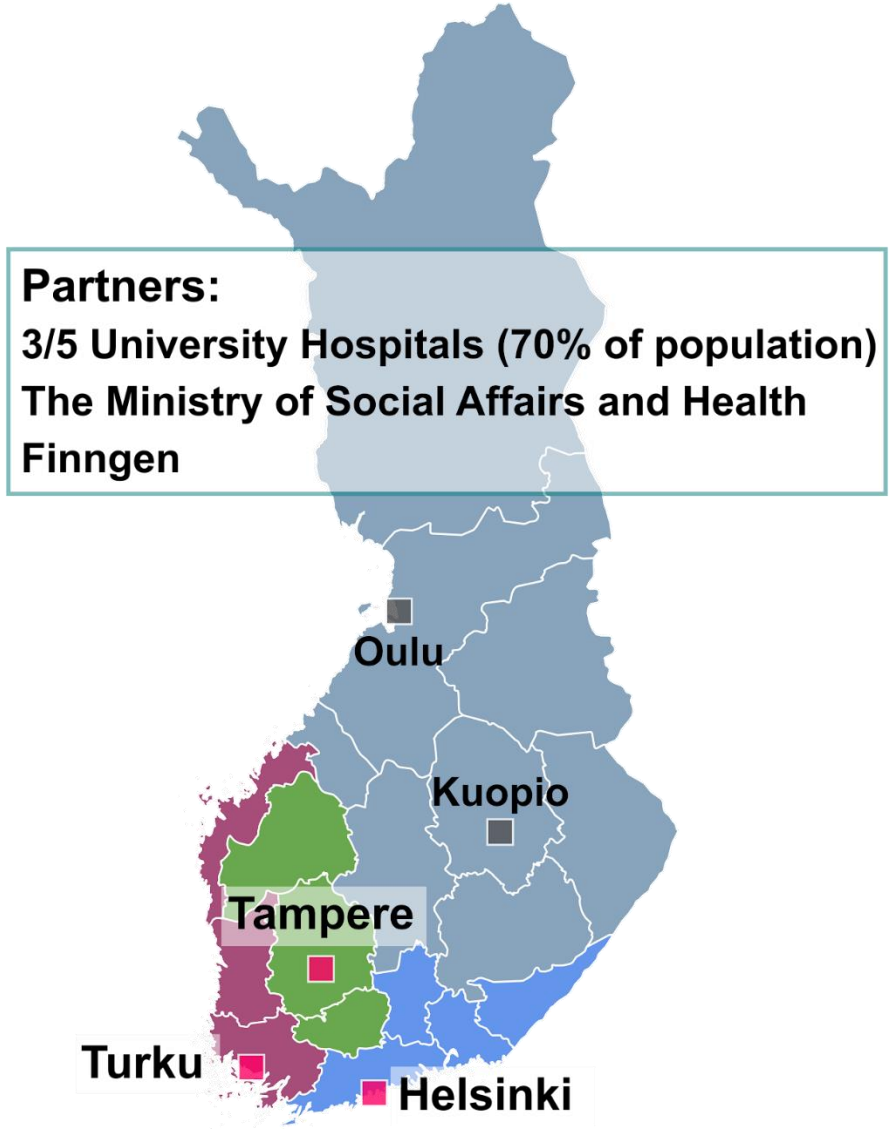
Technical Infrastructure

e.g. secure cloud computing

Data network

HARMONY
EHDEN
Darwin EU
OHDSI
HONEUR

FinOMOP



- Started 2019
- Funded by local and EU grants (EHDEN) => part of hospital IT infrastructure (permanent funding)
- 10.5M hospital patients mapped to OMOP CDM
- Mapping of governmental registries initiated in 2022 (THL, HILMO, avoHILMO, FinRegistry)
- Consortium agreement 01/2024
- Coordinator: THL
- Marketing, contracting: FinBB

AIM: population-based harmonized health data infrastructure by 2025

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

DARWIN EU

UK

1. Clinical Practice Research Datalink (CPRD GOLD)

10. UK Biobank

Netherlands

2. Integrated Primary Care Information

3. Netherlands Comprehensive Cancer Organisation

Belgium

4. IQVIA Belgium Longitudinal Patient Data

France

5. Bordeaux University Hospital

11. Système National des Données de Santé

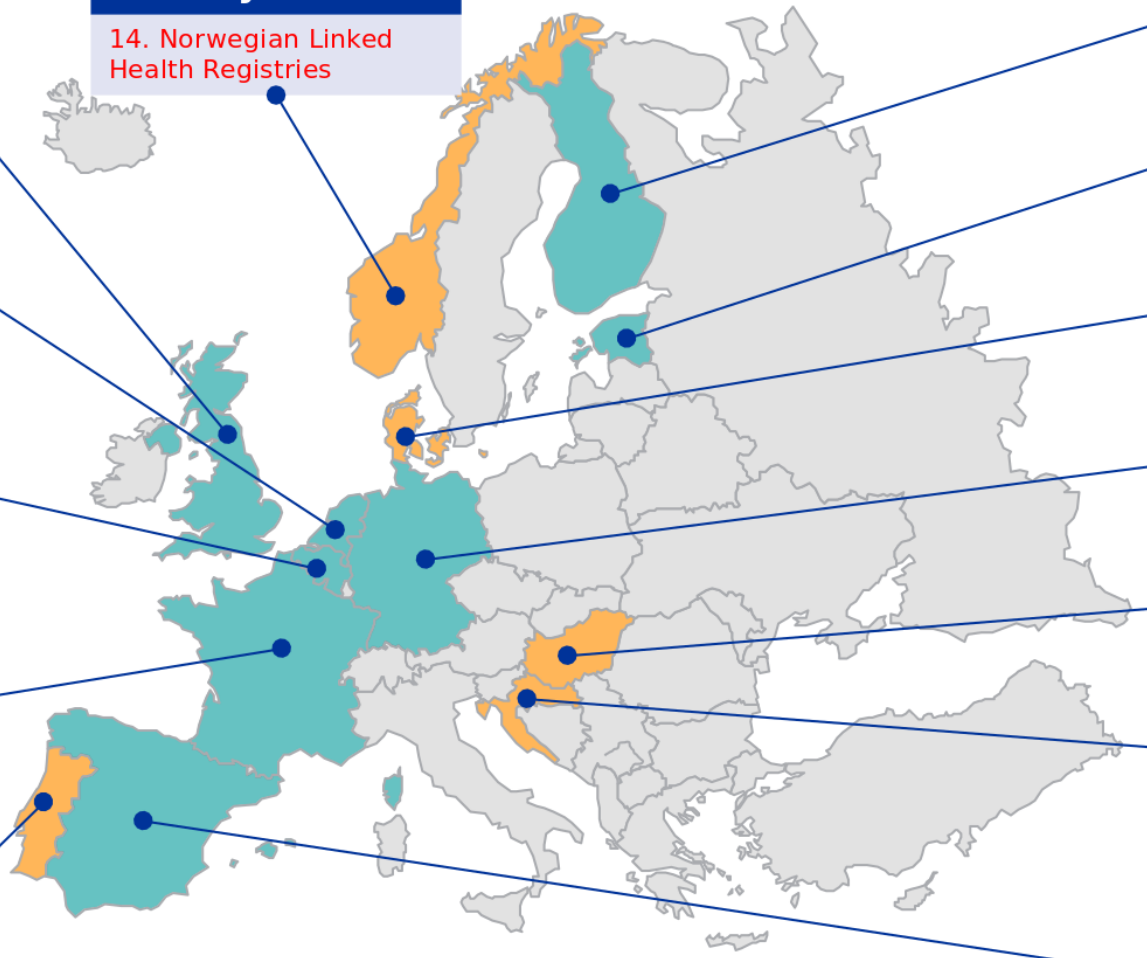
Portugal

19. Unidade Local de Saúde de Matosinhos

20. Egas Moniz Database

Norway

14. Norwegian Linked Health Registries



Finland

15. FinOMOP

Estonia

8. University of Tartu (Biobank)

Denmark

16. Danish Health Data Registries

Germany

9. IQVIA Germany Disease Analyser

Hungary

17. Semmelweis University

Croatia

18. Croatian National public health information system

Spain

6. IDIAPJGol

7. Parc Salut Mar Barcelona, Hospital del Mar (IMIM)

12. BiFAP

13. Valencia Health System Integrated Database

~26 million active patients from Phase I

Adding >100 million active patients from Phase II

Red font - New data partners

additional geographical coverage

iCAN

PLEG pilot 2023: FinOMOP, FIMEA, SITRA

(post-licencing/launch evidence generation, PLEG)

FinOMOP-RWD, 3 university hospitals, data federation

Predefined information request on 3 case examples

- Daratumomab use and outcome
- CART use and outcome
- Spinal muscular atrophy (SMA)

Medaffcon (CRO), local data teams

Aims of the PLEG pilot

- Piloting of OMOP data model and data federation in 3 university hospitals in Finland
- Assessing if OMOP CDM and data federation would be fit for purpose in providing additional evidence for drug regulatory purposes
- Identification of strenghts and weaknesses and next stepts

Some lessons

- The requested information was mostly available

- The usability of the data was evaluated from the point of view of therapeutic and economic evaluation of medical treatments. Currently usable for:
  - budget impact calculations (number of patients)
  - describing the target population of the treatment
  - limited in monitoring impact and resource use

- The indications for use of new drugs are typically very precisely defined, need very granular data. Results must be reported with an accuracy corresponding to the indications for use

- Local procedures for implementation need refining and harmonization

Data harmonization & federation teams & collaborators

Finnish institute for health and welfare

Terhi Kilpi
Anna Hammais
Gustav Klingstedt
Persephone Doupi
Arto Vuori
Jan Magnusson

varha
The wellbeing services county of Southwest Finland

Arho Virkki
Pia Tajanen-Doumbouya
Tommi Kauko
Otto Ettala

HUS Helsinki University Hospital

Marianna Niemi
Perttu Koskenvesa
Annu Kaila
Johanna Niklander
Oscar Brück
Juho Lähteenmaa
Johanna Mattson
Taneli Raivio
Tietohallinto

The Wellbeing Services County of Pirkanmaa

Kati Kristiansson
Sampo Kukkurainen
Leena Hakkarainen

Wellbeing services county of North Savo

Arto Mannermaa
Simo Ryhänen
Jani-Matti Tirkkonen
Arto Vesterbacka

productivity leap

Pasi Rikala
Anna Virtanen

BCB medical

Aaro Mustonen

BC Platforms

Tomi Laitinen

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fimea

Piia Rannanheimo
Minttu Kokko
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Vesa Kiviniemi

FINBB

Marco Hautalahti
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Esa Pitkänen
Valtteri Nieminen
Alexey Ryzhenkov
Salma Rachidi

FINNGEN

Javier Gracia Tabuenca
Tarja Laitinen
Joanne Demmler
Aarno Palotie

Pohde
The Wellbeing Services County of North Ostrobothnia

Minna Mäkiniemi
Jani Tikkanen

DZNE

Joachim Schultze
Hartmut Schultze
Stefanie Warnat-Herresthal

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A COLLABORATION BETWEEN HUS & UNIVERSITY OF HELSINKI

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Prof Kimmo Porkka
Professor of personalised cancer medicine / Chief Physician, University of Helsinki

Dr Christian Dehlendorff
Biostatistical Chief Consultant, Danish Medicines Council

Lars Møller
Access & Value FIND Cluster Lead and Managing Director, Pfizer Denmark

REAL WORLD EVIDENCE
RWE4Decisions Symposium

14 NOV 2024

Developing Real-World Evidence to Deliver Innovation in HTA

BIP Meeting Center, Rue Royale 2/4, 1000 Brussels

Launch of the revised Actions for Stakeholders to Generate better RWE for HTA/Payers

HTA/Payers
Registries
Clinical Teams
Industry
Patients
RWD/Analytics

Thank you for your contributions!

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For more information and to sign up to our mailing list, visit **www.rwe4decisions.com**

Or get in touch via email at **secretariat@rwe4decisions.com**

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