From Sharing to Stewardship: The New Paradigm in European Health Data Governance

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The European Institute for Innovation through Health Data

My Data, Our Health
2nd July 2025, Athens

EHDS – more than a new Regulation

- A pioneering EU initiative
- Not the only, but yet another channel
- A facilitator for EU wide data sharing
- An important game changer

Implications for Stakeholders

- **For governments**: New roles, capacities, and legislation will be needed.
- **For data holders**: New obligations around access, interoperability, and oversight.
- **For data users**: A more structured and predictable access pathway.
- **For patients and the public**: Greater clarity, transparency, and control.

"My data Our Health" *Shaping the Future of Innovation in Cancer Care in Greece*

A purpose oriented multistakeholder Forum	• Data holders (e.g. hospitals, registries, state agencies, also industry) • Data users (e.g. Pharma and MedTech, researchers, clinicians, digital health innovators) • Beneficiaries (e.g. patients, caregivers, public health entities) • Enablers (e.g. regulators, policymakers, ethics bodies, funders)
Objective	Motivate and align policymakers, healthcare and research stakeholders to collectively maximise the opportunities for Greece from the European Health Data Space (EHDS)
End Point	The goal is to culminate in a White Paper capturing shared priorities, insights, and actionable proposals that can inform Greek health policy and legislative frameworks, particularly in the context of the EHDS
Starting Point	Towards a solid understanding of the EHDS across members of the initiative

European Data Strategy

Make the EU a leader in a data-driven society by creating a **single market for data** that ensures Europe's global competitiveness and data sovereignty.

- Unlock the potential of data across sectors and borders
- Empower individuals and businesses with control over their data
- Promote innovation, AI development, and digital transformation
- Foster trust through strong data governance and standards

Key Building Blocks

Governance

Legislation

Infrastructure

Funding: Digital Europe

Laying the foundations - Digital Governance Act

The DGA in Brief

- creates a legal and technical infrastructure for:
  - **Re-use of public sector data**
  - **Data intermediaries** (trust services)
  - **Voluntary data altruism**

sector-neutral

enables data mobility, but does not regulate sector-specific practices or purposes

Beyond the DGA –the EHDS

- The **first sector-specific implementation** of the European Data Strategy
  - Provides **primary use rules** (patient access, health data portability)
  - Establishes **secondary use governance** (e.g. Health Data Access Bodies, permitted purposes)
  - Sets **technical and semantic standards**
  - Builds **HealthData@EU**, a federated infrastructure across Member States

EHDS: From Data Sharing to Data Stewardship

Making the mental switch

- From data protection to data use
- From voluntary sharing to rights-based access and responsible re-use
- From fragmented systems to harmonised European governance
- From passive data holders to accountable data stewards (public bodies, SPEs, HDABs)

- trust-building mechanisms: principles, human oversight, secure processing, control, transparency.

Going beyond the DGA

DGA

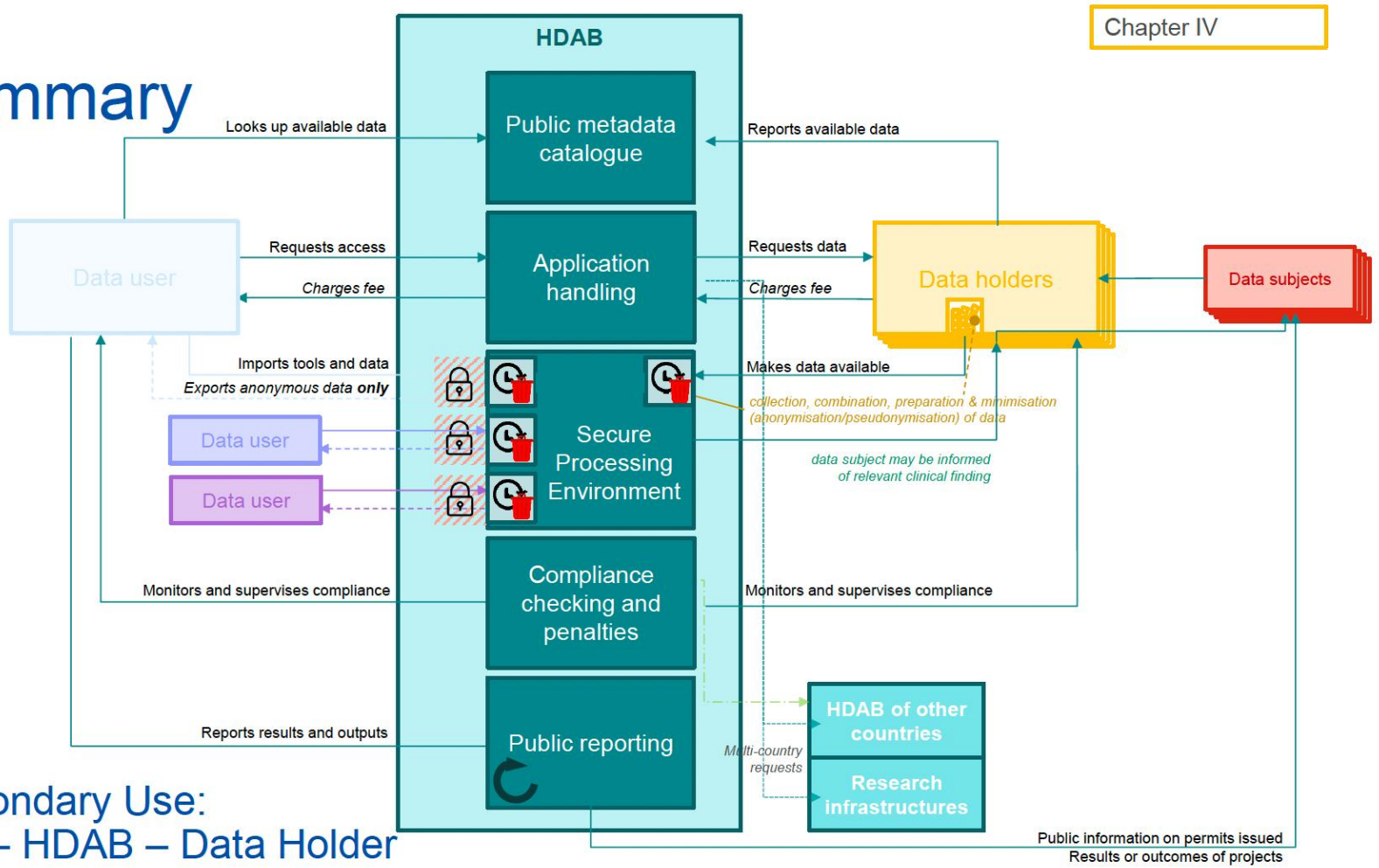
DGA Intermediary = A **data broker** with strong **neutrality and transparency rules**, serving many sectors.

EHDS

EHDS HDAB = A **data access regulator** with legal authority to assess, permit, and monitor sensitive health data use.

Summary

Chapter IV



EHDS Secondary Use: Data User – HDAB – Data Holder

What is novel about the EHDS?

It is not an upgrade — it is a **systemic redesign**

- From national laws to harmonised EU legislation
- From project-by-project solutions to structured, governed access
- From ad hoc committees to new statutory authorities (HDABs)
- From variable, opaque infrastructures to certified, secure environments
- From case-by-case access to codified permitted/prohibited purposes
- From single focus on care or research to coupled care (primary) + reuse (secondary)

Summary of the European Health Data Space Regulation

Professor Dipak Kalra, President of i~HD

The European Institute for Innovation through Health Data

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Common European data spaces

Rich pool of data (varying degree of accessibility)

Free flow of data across sectors and countries

Full respect of GDPR

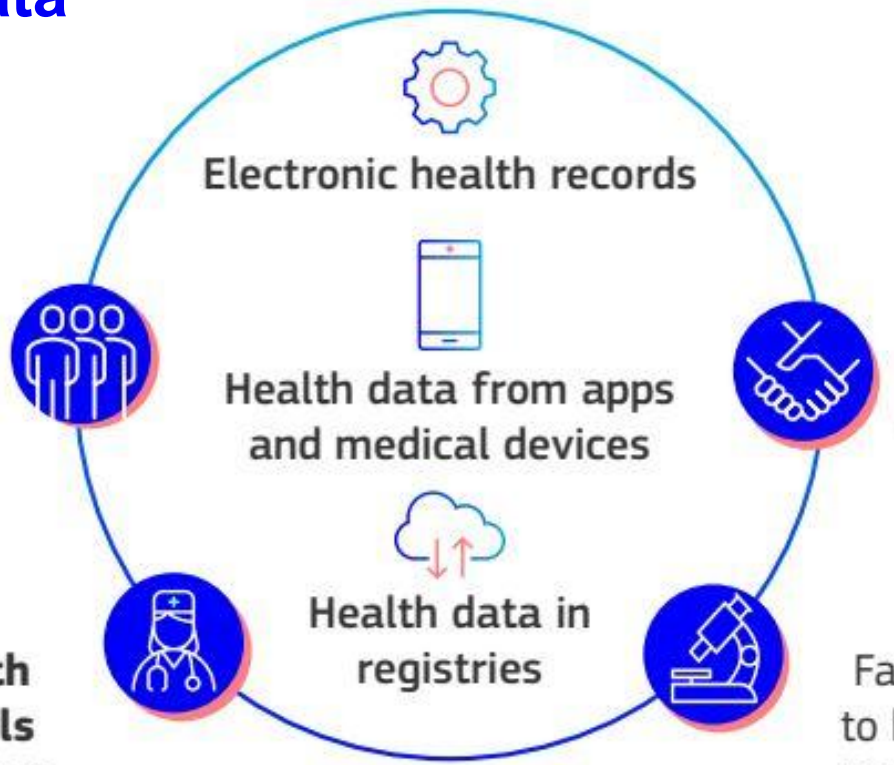
Horizontal framework for data governance and data access

- Technical tools for data pooling and sharing
- Standards & interoperability (technical, semantic)
- Sectoral Data Governance (contracts, licenses, access rights, usage rights)
- IT capacity, including cloud storage, processing and services

European Commission

The European Health Data Space

Primary use of health data



Empower **individuals** to have control over their health data

Enable **health professionals** to have access to relevant health data

Assist **policy makers and regulators** in accessing relevant health data

Facilitate access to health data for **researchers and innovators**

Better diagnosis and treatment:

- improved patient safety
- continuity of care
- improved healthcare efficiency

Better health policy, greater opportunities for research and innovation

Secondary use of health data

The EHDS provisions for Primary Use - health, care, wellness

Natural persons in the EU have increased control over their electronic health data
Better exchange and access to electronic health data to support healthcare delivery

EHR systems must be certified against (to be published) criteria for two "harmonised components"
(1) Must be able to import/export in the European EHR eXchange Format (EEHRxF)
(2) Must be able to log data accesses and provide individuals with transparent access to their audit log
Data quality assurance: semantics, uniformity, consistency of data registration, accuracy and completeness

If they claim interoperability with EHR systems:
Medical devices, in vitro devices, AI components, wellness apps must also be certified

Persons may access their EHR consolidated at MS level, add personal health data but not edit clinical data
Persons have extended GDPR rights to access all EEHRxF data regardless of legal basis, and share with others
Persons may limit access to their EHR and know who has accessed it

Member States must enable HCPs to access their patients' EHRs anywhere in the EU via MyHealth@EU
Member States required to provide digital health and data access rights training to HCPs, patients, the public

Priority EHR data categories for primary use

Plus:

Prescriptions

Lab results

Radiology reports

Discharge summaries

Conformance requirements for EHR systems, devices and wellness applications

European Interoperability component
(European EHR exchange format for priority data)

European Logging component
(audit log of all accesses, visible to the patient)

Within the next 7 years

Mandatory self-assessment for EHR systems
- *and systems that process patient summary data*

Obligatory for medical, in vitro devices and AI
- *if they claim interoperability with EHRs*

+ MDR, IVDR, AI Regs

Optional for wellness apps
- mandatory *if they claim interoperability with EHRs, and must be visibly labelled if certified*

EC and MS to provide testing and certification services

EC to maintain a European register

EHDS Secondary Uses - research, innovation, policy, regulatory, personalised medicine

Researchers, innovators, policy- makers and regulators at EU and Member State level to access relevant electronic health data to promote better diagnosis, treatment and well-being of natural persons, and lead to better and well- informed policies

All data holders have legal obligation to make personal health data available for secondary use
Wide range of data categories, to include data with IP and trade secret sensitivities

Health data sets must be labelled with FAIR metadata and will be catalogued
Data quality labelled (optional): completeness, uniqueness, accuracy, validity, timeliness, consistency, bias

MS must establish Health Data Access Bodies
To grant data access only for published permitted purposes, but not for prohibited purposes
To public and private entities at a proportionate cost, requirement to openly publish analysis results
Aggregated or anonymised, but pseudonymised if there is a justification, approvals and safeguards
Provide data sets through a secure and audited processing environment

Publish information about permits granted and refused, audits, outcomes from using the data, lay summary

Secondary use data categories

Types of data

- Health, healthcare, broad determinants of health
- Socio-economic, environmental, education, occupation
- Behavioural health
- Pathogens
- Genetic, genomic, all ‘omic and molecular data
- Automatically-generated personal health data
- Health insurance, claims, reimbursements

Sources of data

- EHR
- Medical/in vitro devices
- Wellness apps
- Registry data (many kinds)
- Clinical trials, studies, investigations that have ended under the CTR
- Research cohorts, surveys (after first publication)
- Biobanks

Ancillary data

- Treating health professional details
- Aggregated health needs, access to services, healthcare financing

EHDS permitted and prohibited purposes for secondary health data use

Public interests for public and occupational health
- cross-border threats to health
- public health surveillance
- healthcare quality and patient safety
- safety of medicines and devices

Policy making and regulatory activities

Statistics related to health and care

Higher education and teaching in health and care

Scientific research contributing to health, HTA or care
- product and service development and innovation (e.g. medicines)
- training, testing and evaluating of algorithms, digital health tools

Improving and optimising delivery of care

Developing products or services that may legally, socially or economically harm individuals or groups
- illicit drugs, alcoholic beverages, tobacco products
- products or services that cause addiction or contravene public order

Decisions with effects detrimental to a person based on their electronic health data
- e.g. legal, employment, insurance, pension, banking, mortgaging of properties

Decisions that exclude persons or groups, or provide less favourable terms, for products and services

Advertising or marketing activities

Activities in conflict with ethical provisions pursuant to national law

Patient rights to opt out of the secondary use of health data

Patient rights to opt out of secondary data use
across all Member States,
with possible exemptions at Member State discretion

Opt out over-ride

- Only available to public sector bodies, including relevant European agencies, entrusted with carrying out tasks in the area public of public health, for:
  - purposes in the public interest e.g. protection against serious cross-border threats to health
  - research in the public interest e.g. addressing unmet medical needs, including for rare diseases, or emerging health threats
- The over-ride must be justified e.g. no other source of the data

Application procedures

Articles 68, 69

A streamlined procedure across EU

Single application form

Single permit template

Fees based on the complexity and duration of data access.

Data Access Application

For processing personal electronic health data.

Includes **detailed application requirements** such as applicant details, data description, intended use, ethical assessments (where required by MS law), and security measures.

Data can be accessed in **pseudonymised format** unless **anonymised data** suffice for the purpose.

If accepted, the applicant receives a **data permit.**

= direct access to data under stricter conditions.

Data permits are generally granted for up to 10 years with possible extensions.

Data Request

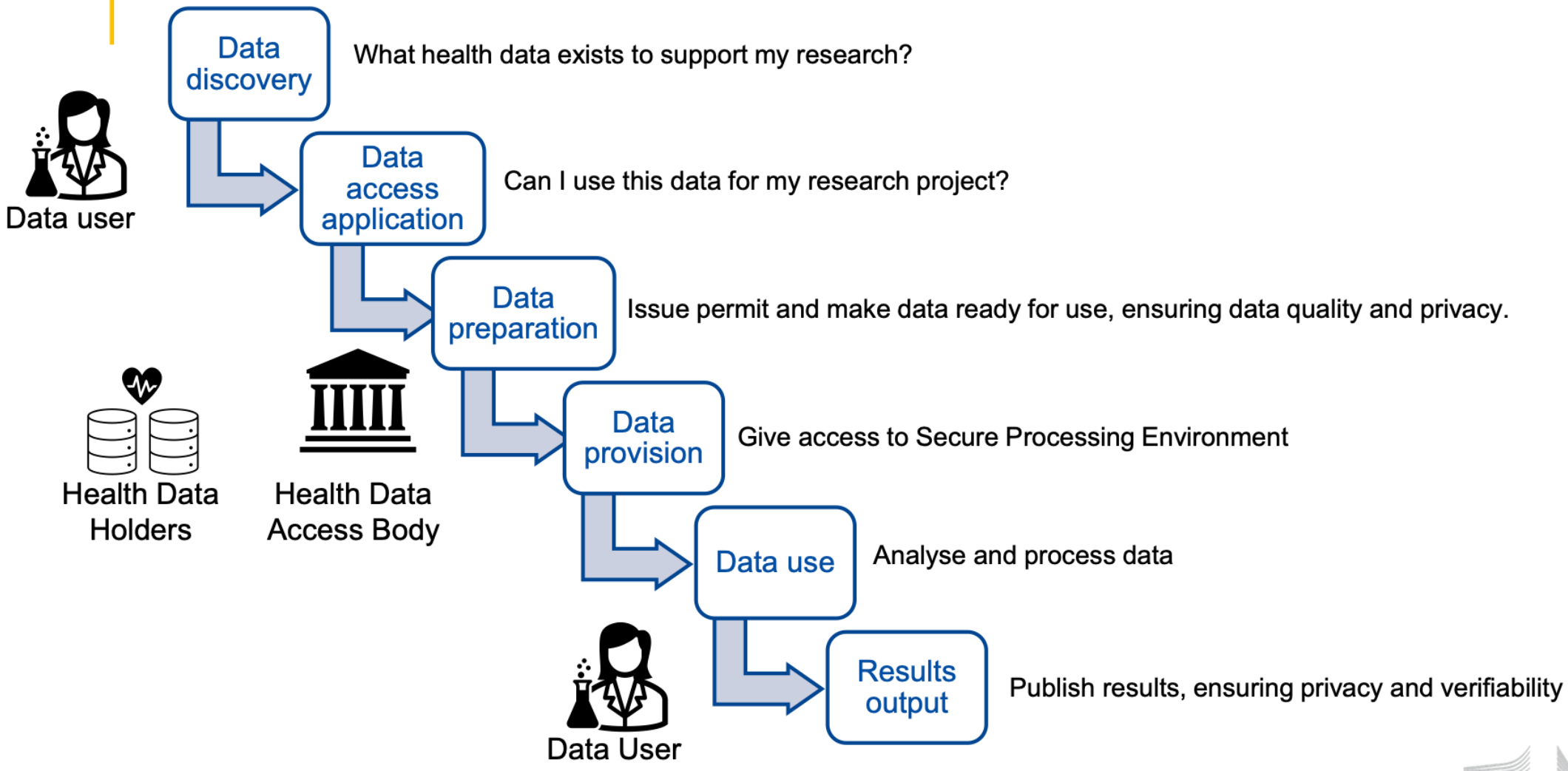
For obtaining answers in **anonymised statistical format** only.

Less stringent application focused on identity, intended use, and safeguards without direct access to personal data.

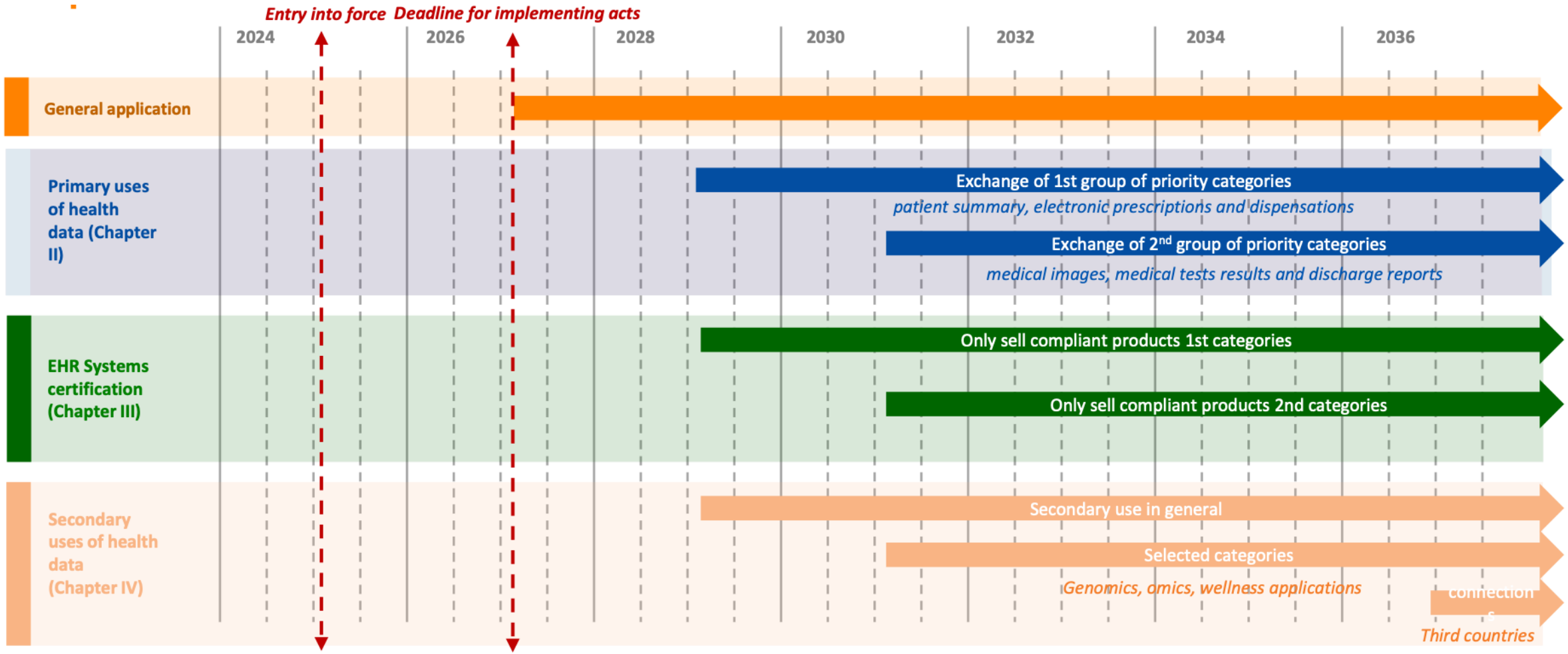
= only **statistical outputs from anonymised data**, suitable for broader or public interest inquiries without personal data access.

European Commission

User journey



Implementation of the EHDS Regulation



FAQ regarding the European Health Data Space Regulation

Bart Vannieuwenhuyse, i~HD Strategic Alliances Advisor

The European Institute for Innovation through Health Data

My Data, Our Health
2nd July 2025, Athens

Some “burning questions” …

1. Must pre-existing arrangements for reusing health data change?
2. Can the EHDS support federated analytics?
3. Does the EHDS only support anonymised data reuse?
4. Does the EHDS impose standards for secondary use data sets?
5. Does the EHDS require data quality assessment and labelling?
6. Will any party holding health data be obliged to make it available for secondary use?
7. What happens with confidential, commercial data for pharma?

https://health.ec.europa.eu/latest-updates/frequently-asked-questions-european-health-data-space-2025-03-05_en

1. Must pre-existing arrangements for reusing health data change?

- Art 1.8 "This Regulation **shall not affect** access to electronic health data for secondary use agreed in the framework of contractual or administrative arrangements between public or private entities."

    - Existing point to point data sharing and data access arrangements may continue as before
    - Large data networks (e.g. federated data networks, cloud based networks) may still operate under their existing terms
        - However, while the use of the EHDS channel is not compulsory the principal legal requirements, **such as the GDPR must always be complied with and the EHDS permitted purposes should be aligned with as closely as possible** – not a way to circumvent obligations
    - The EHDS is a complementary addition, expected to grow to become a large secondary use channel
    - Note that national laws and administrative processes will apply, which may include compliance with Research Ethics Committees or similar review bodies.

2. Can the EHDS support federated analytics?

- Data sets must be placed in a **Secure Processing Environment (SPE)** under the control of a Health Data Access Body
    - The data user may query the data set, as could a computer process acting under the control of the data user
        - Data users could therefore send queries to multiple data sets - within one or more than one country
    - BUT each data set has to be pre-specified and used for a specified permitted purpose
        - It may offer a slow method for case by case federated querying

3. Does the EHDS only support anonymised data reuse?

- Default Rule: Only **De-identified Data** for secondary use of health data - the default is pseudonymised or anonymised data.
    - Data will be made available in anonymised format unless the purpose can only be achieved with data in pseudonymised format. Ethics committee approval might be required
    - A less stringent application process is proposed for extracting only aggregated (statistical format) data
        - This might accelerate the EHDS conduct of federated queries that usually only require aggregated data
    - **Identifiable data** can not be shared (art 66(3)).
        - Strict prohibition on re-identification and data downloads.

4. Does the EHDS impose standards for secondary use data sets?

- For primary use the EHDS will mandate the use of the European EHR exchange format to communicate identifiable patient data for cross-border care
- For secondary use the EHDS does not mandate the use of any particular data standard
    - It does require that the standard that has been used is declared as part of mandatory metadata
    - The adoption of the FAIR principles and compliance with the EHDS data catalogue standards is required

5. Does the EHDS require data quality assessment and labelling

- For primary use the EHDS will require that EHR systems perform basic data quality checking, but no actual quality standards are imposed
- For secondary use the EHDS will specify a data quality and utility label, presently being developed by the QUANTUM project
  - Use of the Quantum-label will be mandatory for data sets held by public bodies and data sets created through public funds
  - Its use will be optional by other data holders e.g. industry
- The EHDS does not specify any minimum quality standards for primary or secondary use

6. Will any party holding health data be obliged to make it available for secondary use?

- Any legal person, public authority, agency or other body in the health or care sectors
- Any legal person developing health, healthcare or care products or services including wellness applications
- Any legal person conducting research related to the healthcare or care sectors

  - Is obliged to make their health data available for reuse via the EHDS
  - Data relating to intellectual property and trade secrets will be specially protected (by HDABs)

NOTE

- natural persons, including individual researchers, and microenterprises are exempted from the obligations of data holders to make data available for secondary use UNLESS Member State Legislation removes this exemption (Art 50)
- Microenterprise = micro enterprise: fewer than 10 employees and an annual turnover (the amount of money taken in a particular period) or balance sheet (a statement of a company's assets and liabilities) below €2 million.

7. What happens with confidential, commercial data for pharma?

- Under the EHDS, the need to protect the IP-rights and trade secrets of data holders **should not be an obstacle** to the re-use of data.
- Companies may **notify** the HDAB if their datasets contain information covered by IP-rights or trade secrets and ask that such data duly protected
- The HDAB is then responsible for ensuring that **relevant protective measures** are put in place.
- If the protection of IP cannot be addressed through protective measures they **must refuse access** to the data
- The data holder has right to complain about the HDABs decision to make data available but **does not have a veto right**.

Patient benefits from the European Health Data Space

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Priority EHR data categories for primary use

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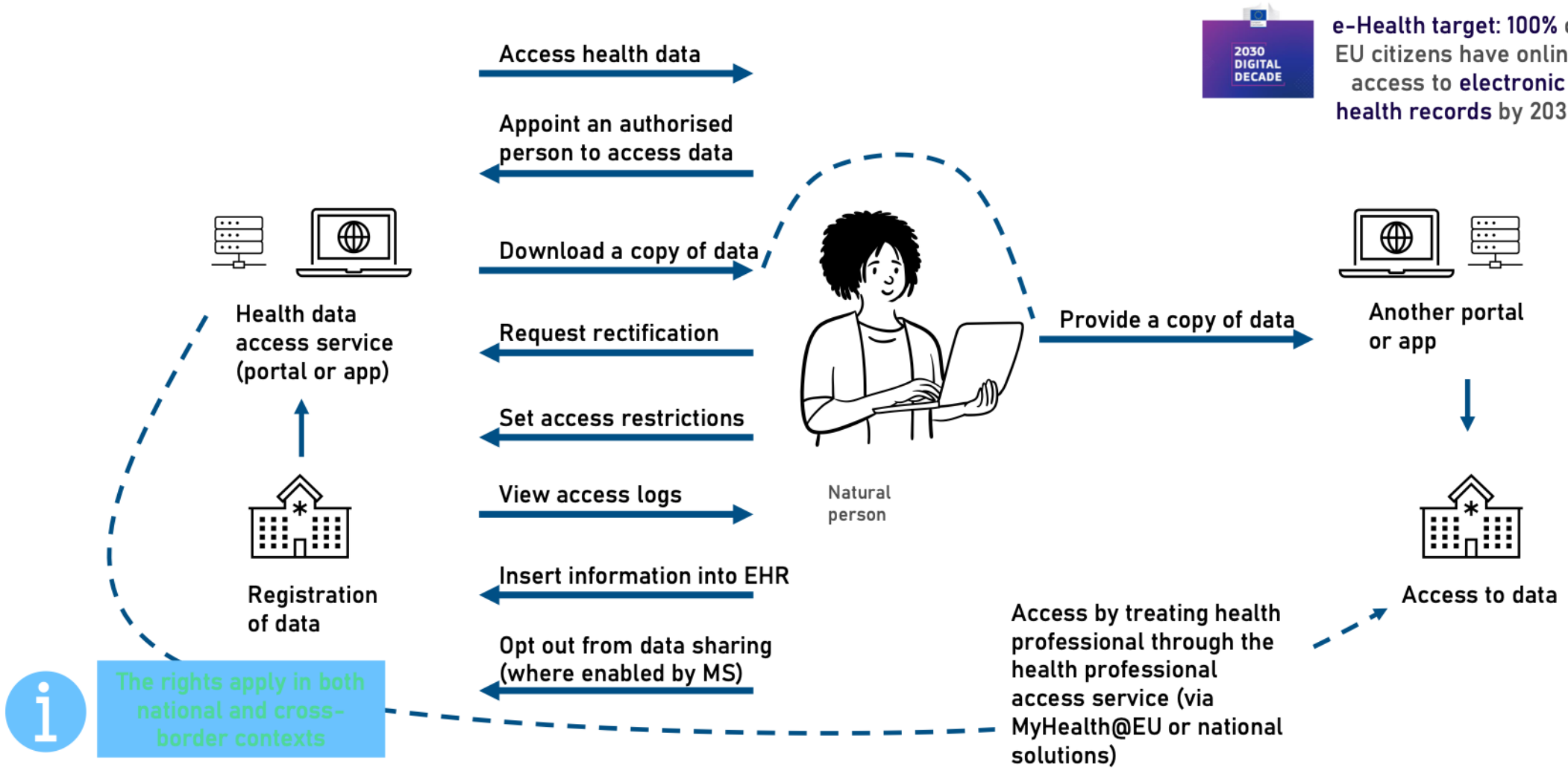
Example health and care benefits (primary use)

- Accurate medications, allergies, conditions to make cross-border emergency care safer, multi-lingual
- Guaranteed interoperability, greater certainty about data quality, for within border continuity of care
- Population level summaries to inform public health insights e.g. during pandemics
- Countries may enrich the exchange format with nationally relevant data e.g. for rare diseases (ORPHAcodes)

Rights of natural persons in primary use



2030 DIGITAL DECADE

e-Health target: 100% of EU citizens have online access to **electronic health records** by 2030

Patients often want to participate in digital health health too!

Track health state

Learn about health conditions, treatment options

Compare with others

Set personal goals

Track progress towards targets

Track bodily function

Adjust dosage to fit lifestyle

Monitor symptoms

Prevention and wellbeing

Assess impact of treatment

Better able to share decision making

Activity, sleep, diet

Document side effects

Contribute their own collected data to research

Know what to discuss with clinical team

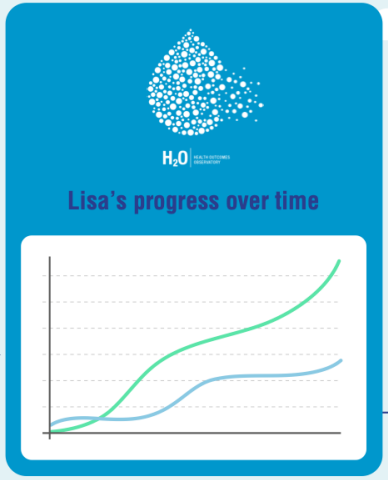
Allow their clinical data to be used for research

Patient-driven healthcare:
The transformative power of H2O
- Health Outcomes Observatory -

H_2O HEALTH OUTCOMES OBSERVATORY

Meet Lisa

A Dutch patient with diabetes and lung cancer, who uses H2O to track the data about her health in a standardised way. She has full control over who she shares the data with and for what scope.



NATIONAL DUTCH H2O OBSERVATORY

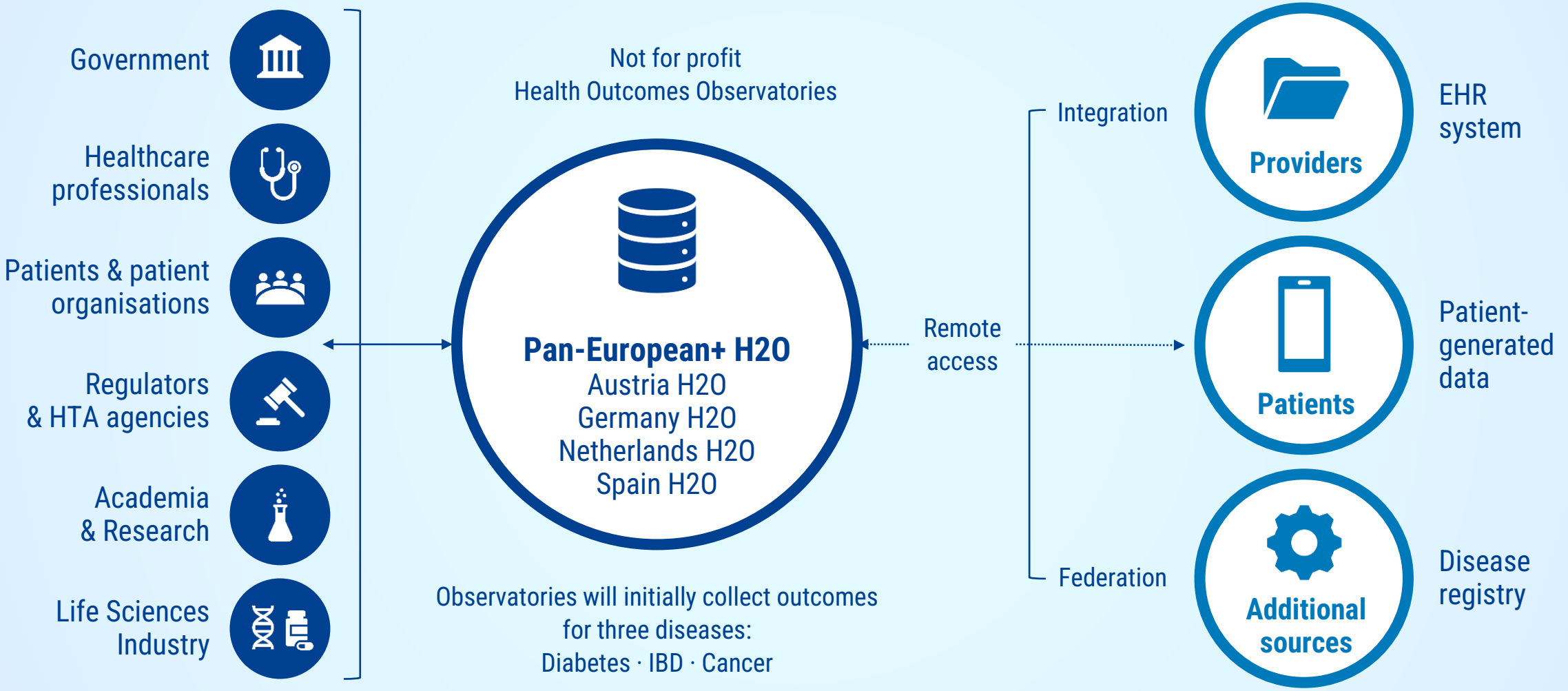
As a result she can:

Compare her data with patients around Europe to gain a better understanding of her diseases.

Have a more effective conversation with healthcare professionals and her caregivers.

Jointly identify if her treatment is achieving the best possible outcomes, and make adjustments if needed.

H2O | First European scale network for health outcomes data



Source: Stamm et al. (2021). NEJM Catalyst

Package leaflet: Information for the user

TRUSOPT® Preservative-Free 20 mg/ml eye drops, solution, single dose container

dorzolamide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What TRUSOPT Preservative-Free is and what it is used for
2. What you need to know before you use TRUSOPT Preservative-Free
3. How to use TRUSOPT Preservative-Free
4. Possible side effects
5. How to store TRUSOPT Preservative-Free
6. Contents of the pack and other information

1. What TRUSOPT PRESERVATIVE-FREE is and what it is used for

TRUSOPT Preservative-Free contains dorzolamide which belongs to a group of medicines called "carbonic anhydrase inhibitors".

This medicine is prescribed to lower raised pressure in the eye and to treat glaucoma. This medicine can be used alone or in addition to other medicines which lower the pressure in the eye (so-called beta-blockers).

2. What you need to know before you use TRUSOPT Preservative-Free

Do not use TRUSOPT Preservative-Free
- if you are allergic to dorzolamide hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney impairment or problems, or a prior history of kidney stones.

If you are not sure whether you should use this medicine, contact your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using TRUSOPT Preservative-Free.

Tell your doctor or pharmacist about any medical problems you have now or have had in the past, including eye problems and eye surgeries, and about any allergies to any medications.

If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately.

If you suspect that TRUSOPT Preservative-Free is causing an allergic reaction (for example, skin rash, severe skin reaction, or itching), stop using this medicine and contact your doctor immediately.

If you wear contact lenses, you should consult your doctor before using TRUSOPT Preservative-Free.

Use in children
TRUSOPT (preserved formulation) has been studied in infants and children less than 6 years of age who have raised pressure in the eye(s) or have been diagnosed with glaucoma. For more information talk to your doctor.

Use in elderly
In studies with TRUSOPT (preserved formulation), the effects of this medicine were similar in both elderly and younger patients.

Use in patients with liver impairment
Tell your doctor about any liver problems you now have or have suffered from in the past.

Other medicines and TRUSOPT PRESERVATIVE-FREE
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines (including eye drops). This is particularly important if you are taking another carbonic anhydrase inhibitor such as acetazolamide, or a sulpha drug.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy
You should not use this medicine during pregnancy. Tell your doctor if you are pregnant or intend to become pregnant.

Breast-feeding
You should not use this medicine during breast-feeding. Tell your doctor if you are breast-feeding or intend to breast-feed.

Driving and using machines
No studies on the effects on the ability to drive or use machines have been performed. There are side effects associated with TRUSOPT Preservative-Free, such as dizziness and blurred vision, which may affect your ability to drive and/or operate machinery. Do not drive or operate machinery until you feel well or your vision is clear.

3. How to use TRUSOPT Preservative-Free

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The appropriate dosage and duration of treatment will be established by your doctor.

When this medicine is used alone, the recommended dose is one drop in the affected eye(s) in the morning, in the afternoon and in the evening.

If your doctor has recommended you use this medicine with a beta-blocker eye drop to lower eye pressure, then the recommended dose is one drop of TRUSOPT Preservative-Free in the affected eye(s) in the morning and in the evening.

If you are using TRUSOPT Preservative-Free with another eye drop, the drops should be instilled at least 10 minutes apart.

Do not change the dose of the drug without consulting your doctor.

Do not allow the tip of the single dose container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the single dose container, wash your hands before using this medicine and keep the tip of the single dose container away from contact with any surface.

Instructions for use:

The solution from one individual single dose container of TRUSOPT Preservative-Free is to be used immediately after opening for administration to the affected eye(s). Since sterility cannot be maintained after the individual single dose container is opened, a new container must be opened prior to each use and must be discarded immediately after administration. Each single dose container contains enough solution for both eyes.

1. Open the foil sachet which contains the individual single dose containers.
2. First wash your hands then break off one single dose container from the strip and twist open the top of the single dose container as shown.

3. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and eye as shown.

4. Put one drop in the affected eye(s) as directed by your doctor.
5. After putting the drop into the eye, throw away the used single dose container even if there is solution remaining to avoid contamination of the preservative free solution.
6. Store the remaining containers in the foil sachet; the remaining containers must be used within 15 days after opening of the sachet. If there are any containers left 15 days after opening the sachet they should be safely thrown away and a fresh sachet opened. It is important to continue to use the eye drops as prescribed by your doctor.

If you use more TRUSOPT Preservative-Free than you should

10. Discard the single-dose container after use. Do not keep it to use it again. Since sterility cannot be maintained after the individual single-dose container is opened, a new container must be opened prior to each use.
11. Place the unopened single-dose containers back in the sachet. Place the opened sachet in the carton. The unopened containers must be used within 1 month after opening the sachet.

If you use Fixapost with other eye drops
Wait at least 5 minutes between using Fixapost and using the other eye drops.

If you use more Fixapost than you should
If you put too many drops in your eye you may experience some minor irritation in your eye and your eyes may water and turn red. This should pass but if you are worried contact your doctor for advice.

If you swallow Fixapost
If you swallow Fixapost accidentally you should contact your doctor for advice. If you swallow a lot of Fixapost you may feel sick, have stomach pains, feel tired, flushed and dizzy and start to sweat.

If you forget to use Fixapost
Carry on with the usual dosage at the usual time. Do not use a double dose to make up to the dose you have forgotten. If you are unsure talk to your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
You can usually carry on using the drops, unless the effects are serious. If you are worried, talk to a doctor or pharmacist. Do not stop using Fixapost without speaking to your doctor.

Listed below are the known side effects of using Fixapost. The most important side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that Fixapost might cause serious changes in the way your heart works. If you notice changes in your heart rate or heart function you should speak to a doctor and tell him or her you have been using Fixapost.

The following are known side effects of using Fixapost:

Very common (may affect more than 1 in 10 people):
- A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris. If you have mixed-colour eyes (blue-brown, grey-brown, yellow-brown or green-brown) you are more likely to see this change than if you have eyes of one colour (blue, grey, green or brown eyes). Any changes in your eye colour may take years to develop. The colour change may be permanent and may be more noticeable if you use Fixapost in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after Fixapost treatment is stopped.

Common (may affect up to 1 in 10 people):
- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye) and eye pain.

Uncommon (may affect up to 1 in 100 people):
- Headache,
- Redness of the eye, eye infection (conjunctivitis), blurred vision, watery eyes, inflammation of the eyelids, irritation or disruption of the surface of the eye,
- Skin rashes or itching (pruritus),
- Nausea, vomiting.

Other side effects
Like other medicines used in the eyes, Fixapost (latanoprost and timolol) is absorbed into the blood. The incidence of side effects after using eye drops is lower than when medicines are, for example, taken by mouth or injected.
Although not seen with Fixapost, the following additional side effects have been seen with the medicines in Fixapost (latanoprost and timolol) and therefore might occur when you use Fixapost. The listed side effects include reactions seen within the class of beta-blockers (e.g. timolol) when used for treating eye conditions:
- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).
- Generalised allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs and can obstruct the airway which may cause difficulty swallowing or breathing, hives or itchy rash, localised and generalised rash, itchiness, severe sudden life-threatening allergic reaction.
- Low blood glucose levels.
- Dizziness.
- Difficulty sleeping (insomnia), depression, nightmares, memory loss, hallucination.
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), unusual sensations like pins and needles, and headache.
- Swelling at the back of the eye (macular oedema), fluid filled cyst within the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus).
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed), double vision.
- Darkening of the skin around the eyes, changes to the eyelashes and fine hairs around the eye (increased number, length, thickness and darkening), changes to the direction of eyelash growth, swelling around the eye, swelling of the coloured part of the eye (iritis/uveitis), scarring of the surface of the eye.
- Whistling/ringing in the ears (tinnitus).
- Angina, worsening of angina in patients who already have heart disease.
- Slow heart rate, chest pain, palpitations (awareness of heart rhythm), oedema (fluid build-up), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build-up), a type of heart rhythm disorder, heart attack, heart failure.
- Low blood pressure, poor blood circulation which makes the fingers and toes numb and pale, cold hands and feet.
- Shortness of breath, constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough, asthma, worsening of asthma.
- Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash.
- Joint pain, muscle pain not caused by exercise, muscle weakness, tiredness.
- Sexual dysfunction, decreased libido.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

UK
The Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fixapost

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton, sachet and single-dose container. The expiry date refers to the last day of that month. This medicine does not require any special temperature storage conditions.
After first opening of the sachet: use the single-dose containers within 1 month.
Write down the date of first opening on the sachet.
After first opening of the single-dose container: use immediately and discard the single-dose container after use.
Keep the unused single-dose containers in the opened sachet in order to protect them from light.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fixapost contains
The active substances are latanoprost 50 micrograms/ml and timolol (as timolol maleate) 5 mg/ml.
The other ingredients are: macrogolglycerol hydroxystearate, sorbitol, macrogol, carbomer, disodium edetate, sodium hydroxide (for pH-adjustment), water for injections.

What Fixapost looks like and contents of the pack
This medicinal product is presented as an eye drops, solution in single-dose container. The solution is a slightly yellow and opalescent preservative free solution, practically free from particles presented in single-dose containers packed in a sachet of 5 units, each single-dose container holding 0.2 ml of product. A pack size contains 30 (6 x 5) or 90 (18 x 5) single-dose containers.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Laboratoires THEA
12 rue Louis Blériot
63017 Clermont-Ferrand Cedex 2
France

Manufacturer
EXCELVISION
27, rue de la Lombardière
07100 Annonay
France

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria, Czech Republic, France, Ireland, Italy, Poland, Slovakia, United Kingdom.....Fixapost
Belgium, Bulgaria, Cyprus, Germany, Greece, Spain, Luxembourg, The Netherlands.....Fixaprost
Denmark, Estonia, Finland, Iceland, Lithuania, Latvia, Norway, Sweden.....Fixopost
Croatia, Slovenia.....Fixalpost
Romania.....Fixanpost
Portugal.....Monoprost Duo

This leaflet was last revised in 03/2022

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharmaceuticals Ltd in UK, telephone number 0345 521 1290, or THEA Pharma Ltd in Ireland, telephone number +44 (0) 345 521 1290

Théa

N23471J30ASP/0322

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Fixapost® 50 micrograms/ml + 5 mg/ml eye drops, solution in single-dose container

latanoprost / timolol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fixapost is and what it is used for
2. What you need to know before you use Fixapost
3. How to use Fixapost
4. Possible side effects
5. How to store Fixapost
6. Contents of the pack and other information

1. What Fixapost is and what it is used for

Fixapost contains two medicines: latanoprost and timolol. Latanoprost belongs to a group of medicines known as prostaglandin analogues. Timolol belongs to a group of medicines known as beta-blockers.
Latanoprost works by increasing the natural outflow of fluid from the eye into the bloodstream. Timolol works by slowing the formation of fluid in the eye.
Fixapost is used to reduce the pressure in your eye if you have conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within your eye, eventually affecting your eyesight. Your doctor will usually prescribe you Fixapost when other medicines have not worked adequately.

2. What you need to know before you use Fixapost

Fixapost can be used in adult men and women (including the elderly), but is not recommended for use if you are less than 18 years of age.

Do not use Fixapost:
- if you are allergic (hypersensitive) to latanoprost, timolol, beta-blockers, or any of the other ingredients of this medicine (listed in section 6),
- if you have now or have had in the past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough),
- if you have serious heart problems or heart rhythm disorders.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Fixapost if you have now or have had in the past:
- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure,
- disturbances of heart rate such as slow heart beat,
- breathing problems, asthma or chronic obstructive pulmonary disease,
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome),
- diabetes as timolol may mask signs and symptoms of low blood sugar,
- overactivity of the thyroid gland as timolol may mask signs and symptoms,
- you are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past,
- you suffer from eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision),
- you know that you suffer from dry eyes,
- you wear contact lenses. You can still use Fixapost but follow the instructions for contact lens wearers in section 3,
- you know that you suffer from angina (particularly a type known as Prinzmetal angina),
- you know that you suffer from severe allergic reactions that would usually require hospital treatment,
- you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV).

Tell your doctor before you have an operation that you are using Fixapost as timolol may change effects of some medicines used during anaesthesia.

Other medicines and Fixapost
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including using eye drops and medicines obtained without a prescription.
Fixapost can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes.
In particular, speak to your doctor or pharmacist if you know that you are taking any of the following types of medicine:
- Prostaglandins, prostaglandin analogues or prostaglandin derivatives,
- Beta-blockers,
- Epinephrine,
- Drugs used to treat high blood pressure such as oral calcium channel blockers, guanethidine, antiarrythmics, digitalis glycosides or parasympathomimetics,
- Quinidine (used to treat heart conditions and some types of malaria),
- Antidepressants known as fluoxetine and paroxetine.

Fixapost with food and drink
Normal meals, food or drink have no effect on when or how you should use Fixapost.

Pregnancy, breast-feeding and fertility
Do not use Fixapost when you are pregnant or breast-feeding.
Fixapost may get into your milk.
Latanoprost and timolol have been found to have no effect on male or female fertility in animal studies.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
When you use Fixapost your vision may become blurred for a short time. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again.

Fixapost contains macrogolglycerol hydroxystearate (derived from castor oil) which may cause skin reactions.

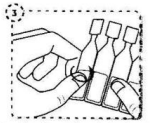
3. How to use Fixapost

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose for adults (including the elderly) is one drop once a day in the affected eye(s). Do not use Fixapost more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.
Use Fixapost as instructed by your doctor until your doctor tells you to stop.
Your doctor may want you to have extra checks on your heart and circulation if you use Fixapost.

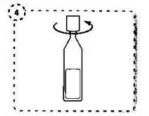
Contact lens wearers
If you wear contact lenses, you should remove them before using Fixapost. After using Fixapost you should wait 15 minutes before putting your contact lenses back in.

Instructions for use
This medicine is intended to be administered into the eye.

Please follow these instructions to use the drops:
1. Wash your hands and sit or stand comfortably.
2. Open the sachet containing 5 single-dose containers. Write down the date of first opening on the sachet.
3. Break off one single-dose container from the strip.



4. Twist open the top of the single-dose container as shown. Do not touch the tip after opening the container.



5. Use your finger to gently pull down the lower eyelid of your affected eye.
6. Place the tip of the single-dose container close to, but not touching your eye.
7. Squeeze the single-dose container gently so that only one drop goes into your eye, then release the lower eyelid.

8. Press a finger against the corner of the affected eye by the nose. Hold for 2 minutes while keeping the eye closed.

9. Repeat in your other eye if your doctor has told you to do this. Each single-dose container contains enough solution for both eyes.

Fixapost® 50 micrograms/ml + 5 mg/ml eye drops, solution in single-dose container

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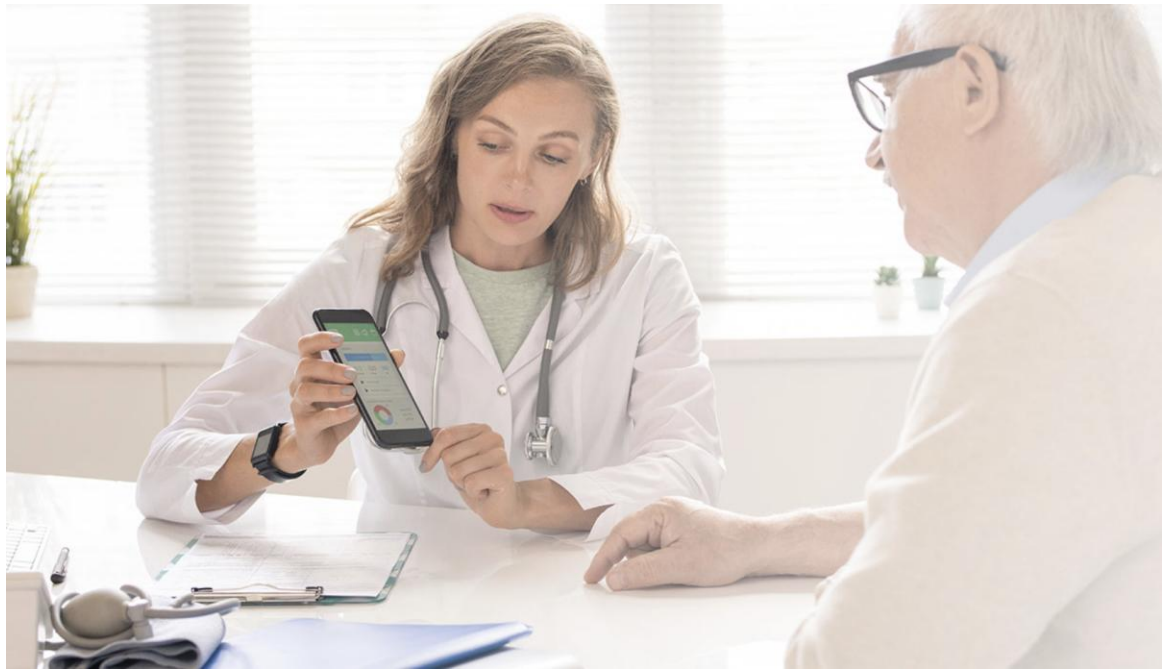
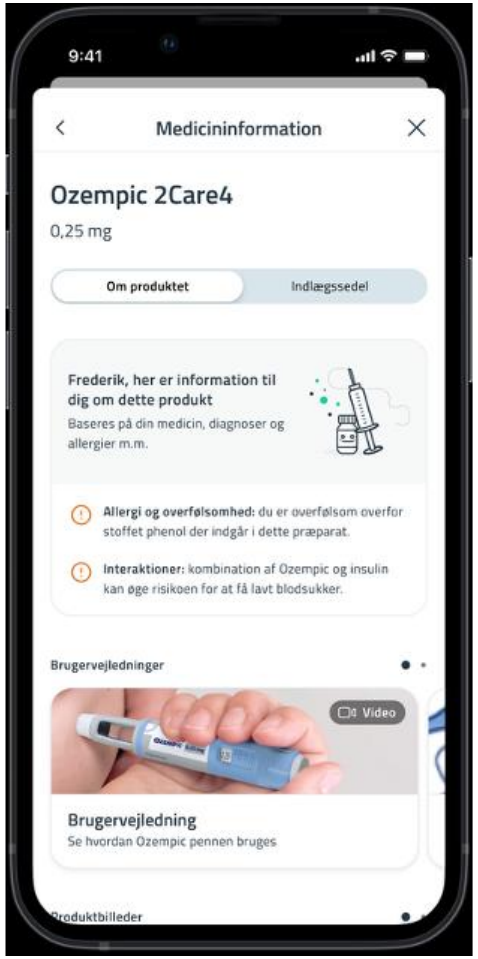
Medicines information for patients

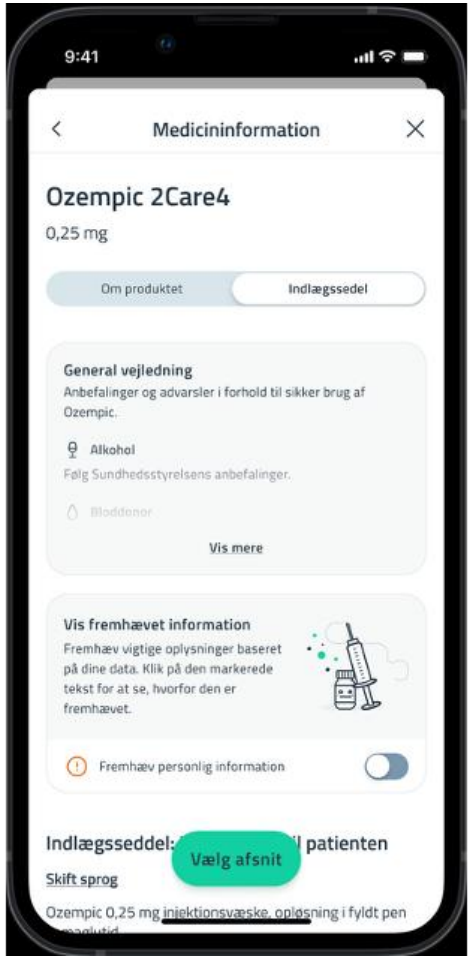
- Equip and empower citizens with digital information tools, the **Gravitate Lens (G-Lens)**
- offering trustworthy, up-to-date and personalised medicines information sourced from the ePI
- targeting
  - safe use of medicines
  - confident, active, and responsive in their patient journey
  - better health outcomes and quality of life

Gravitate Health



Example screen shots of personalised patient information

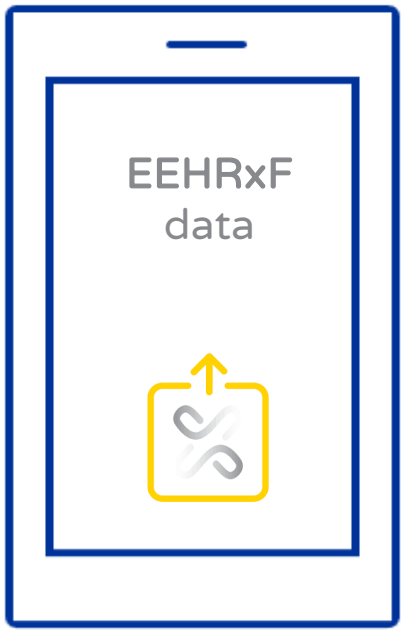




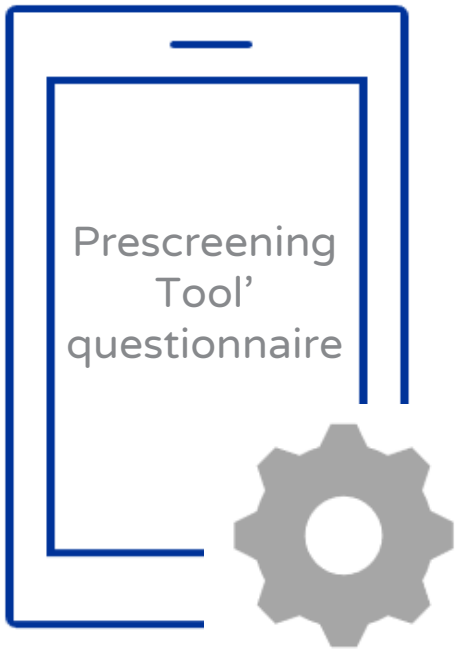
Patient pre-screening

Camille is willing to know if a clinical trial is compatible with their health condition

Camille
45 years
Ulcerative Colitis
Adalimumab
No cancer



Data Sharing



Verifies patient compatibility

with a trial in a hospital in Athens

Example patient benefits from the secondary use of health data

- Accelerated personalised medicine and rare disease research, especially multi-country
- Easier and faster public health evidence for decision making e.g. during pandemics
- Greater data access for health systems planning e.g. unmet needs, care pathway optimisation
- More representative data for AI development (lower risk of AI bias)

Discussion of the patient benefits

Primary use benefits

- Accurate medications, allergies, conditions to make cross-border emergency care safer, multi-lingual
- Guaranteed interoperability, greater certainty about data quality for within border continuity of care
- Population level summaries can inform public health insights e.g. during pandemics
- Countries can enrich the exchange format with nationally relevant data

Secondary use benefits

- Accelerated personalised medicine and rare disease research, especially multi-country
- Easier and faster public health evidence for decision making e.g. during pandemics
- Greater data access for health systems planning
- More representative data for AI development (lower risk of AI bias)

Industry innovation panel

How can we enable responsible and timely access to cancer data?

Bart Vannieuwenhuyse (i~HD)
Ioannis Kotsipoulos (PIF)
Panos Bassios (MSD)

The European Institute for Innovation through Health Data

My Data, Our Health
2nd July 2025, Athens

Real World Data – potential from an industry perspective

Research & Development

Discovery: scientific insights in
- Patient pathways
- Disease epidemiology
- Unmet medical need
- Cohort characteristics

Clinical trials optimization
- Protocol feasibility
- Improved trial design
- Population identification / site selection
- Patient enrollment
- RWD/E studies

Market Access

Value-based reimbursement
- Insights into cost effectiveness
- Assessment of comparative effectiveness
- Estimate budget impact
- Stratify patient population for optimal therapeutic response and safety

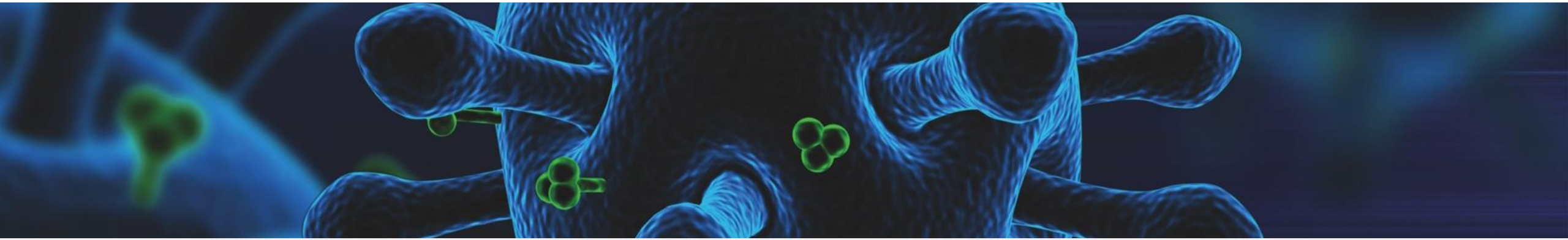
Pay-for-performance
- Monitor success rates for managed entry agreements

Patient Outcomes

Monitoring real world usage
- Safety / pharmacovigilance
- Effectiveness
- Adherence
- Active patient monitoring
- Benchmarking of outcomes with caregivers / patients

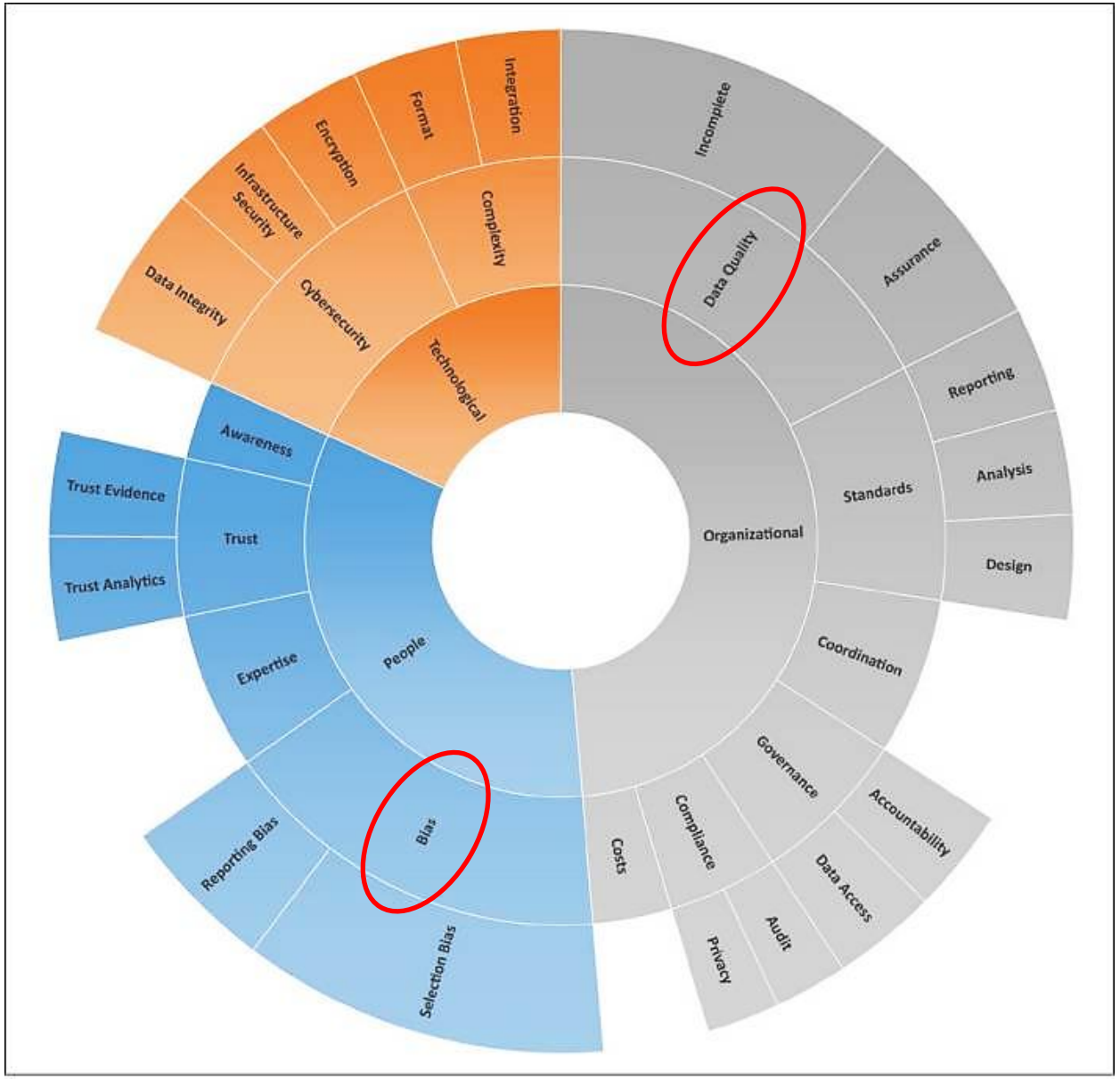
End-to-end RWE management
- Less waste and prescribing errors
- PRO/PRE analysis – personalization of treatment
- Pathway disease modelling

However, there are many challenges in reuse of health data



- Privacy, legal and ethical issues
- Ownership – right to use
- Data in silos
- Semantic chaos – need for practical solutions on interoperability
- Data quality – “horses for courses”
- Contractual barriers
- Digital pipelines for linking and sharing
- Building **trust** among stakeholders

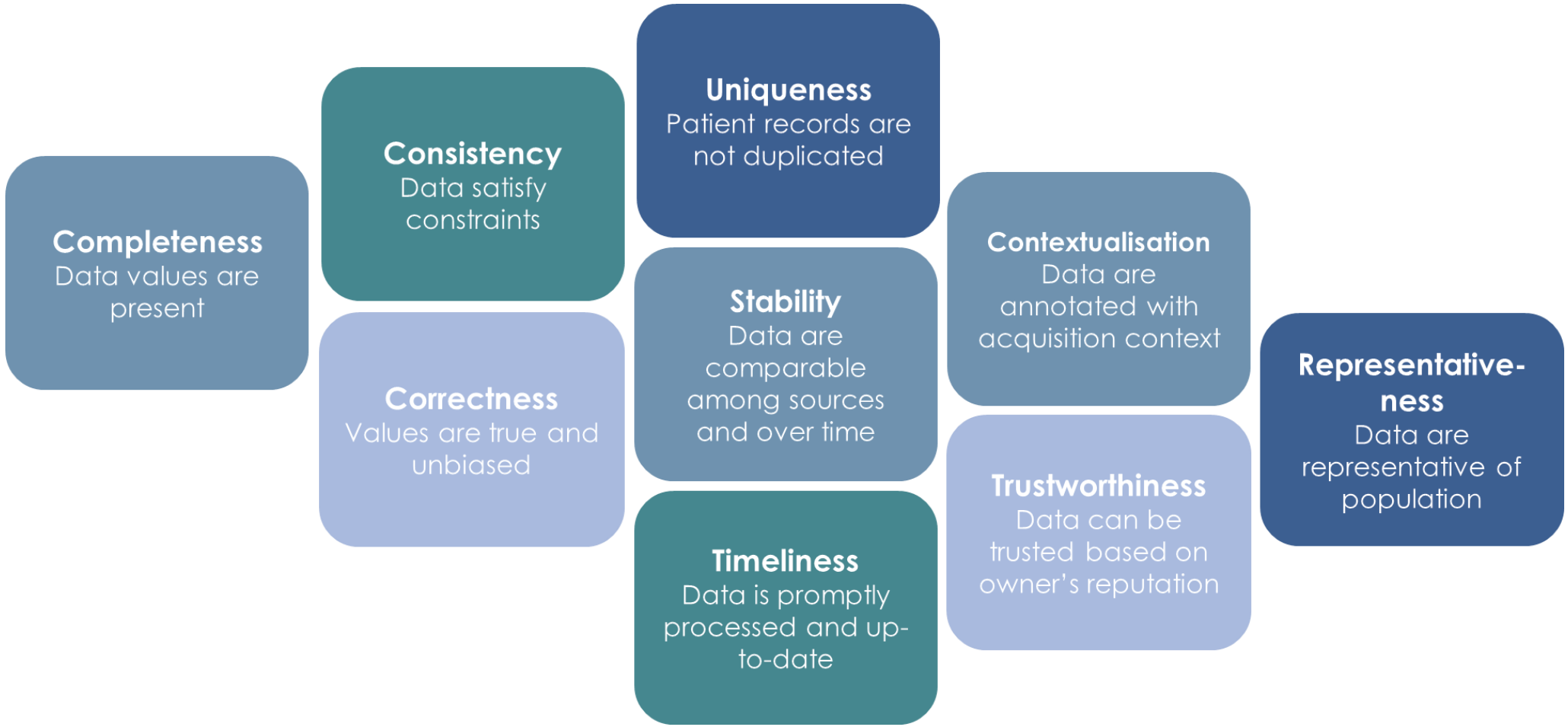
Potential challenges with RWD



The Real-World Data Challenges Radar: A Review on the Challenges and Risks regarding the Use of Real-World Data

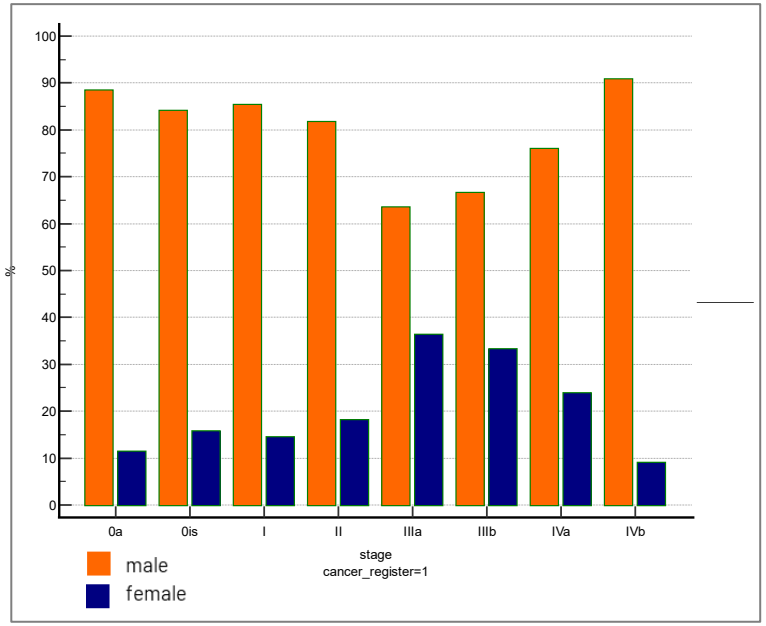
Frank Grimberg et al
Digit Biomark 2021;5:148–157

Data quality dimensions



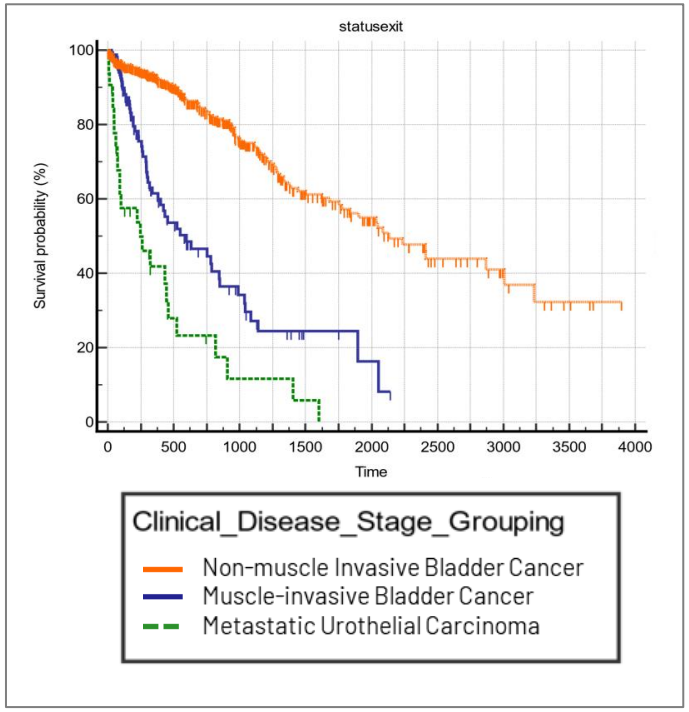
Yet – good results can be had …

Bladder Cancer



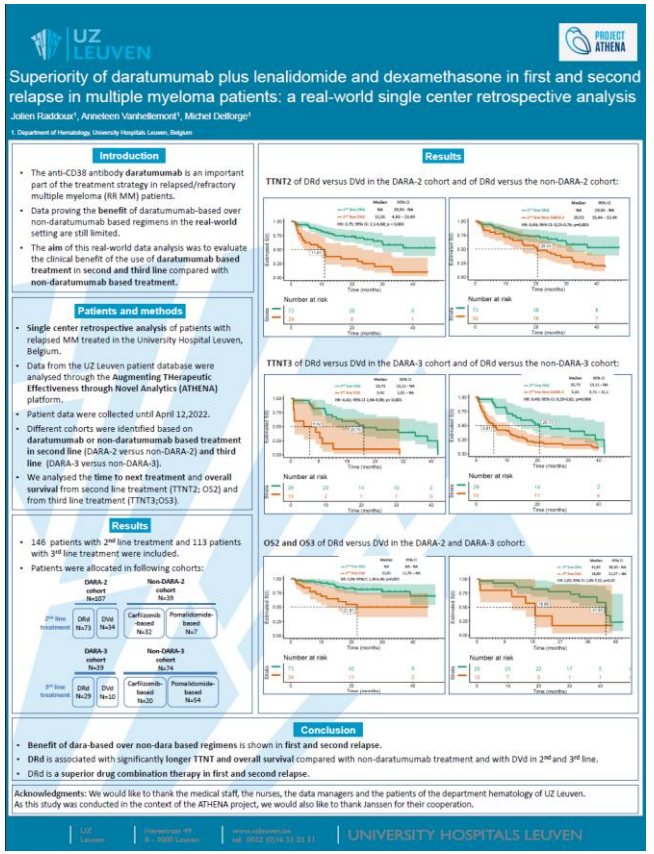
Combination MZG + Cancer-registry data

Bladder Cancer



Combination MZG + Cancer-registry data

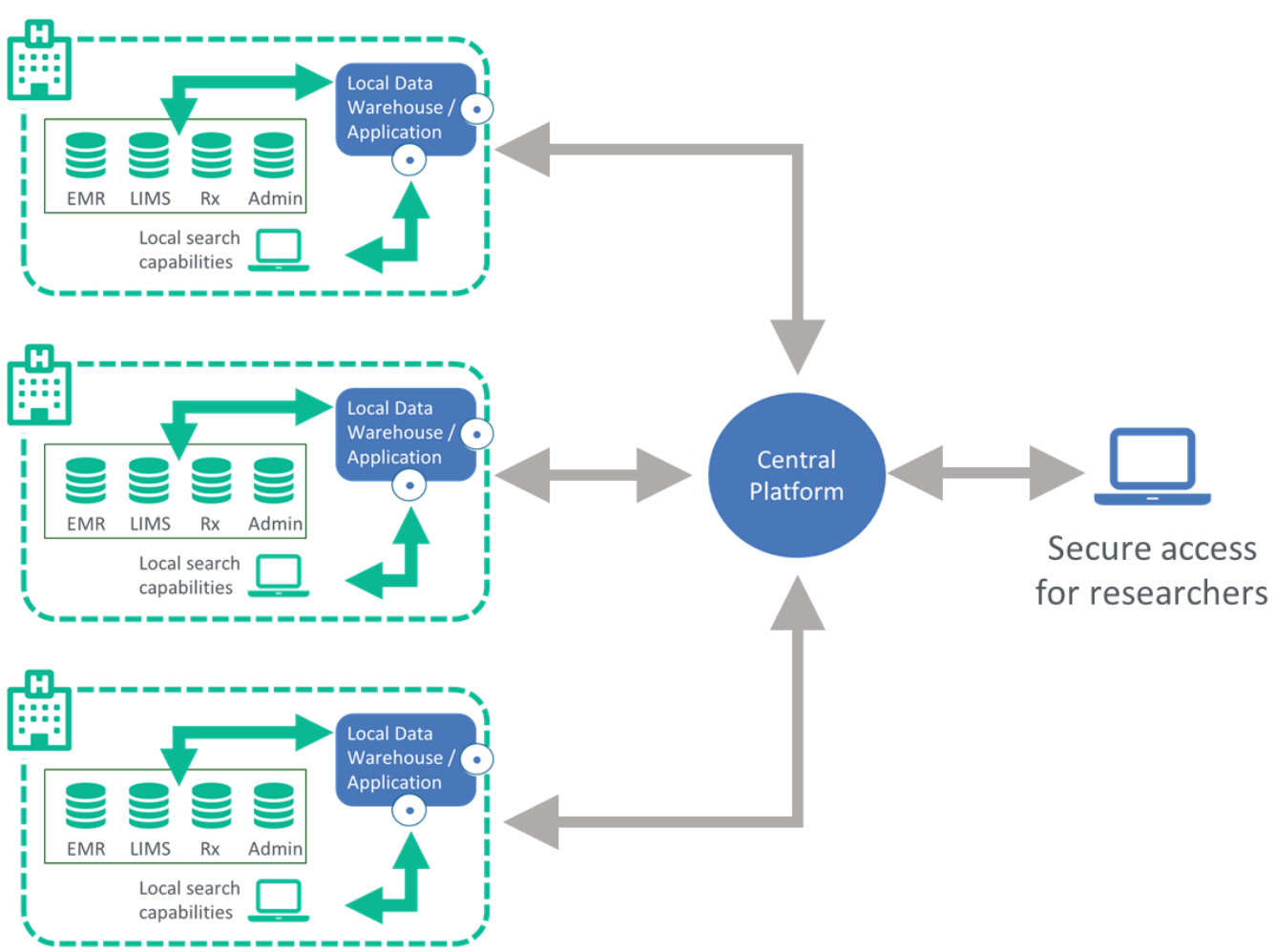
Multiple Myeloma



Hi-Q in-house hospital data

MZG = hospital reimbursement data in Belgium

Privacy by design – Federated Data Networks



Benefits of federated networks

- Data remains under the control of the data owner
- Locally required legal and ethical approvals apply
- No patient level data leaves the owner's site, only aggregated counts, thereby ensuring patient privacy
- GDPR – *'Privacy by Design'*
- Analysis is "brought to the data" rather than creating central data repository
- Use of common data model allows for efficient search / analysis across multiple data sets
- Requires close collaboration with data owners which builds trust

Panel discussion …

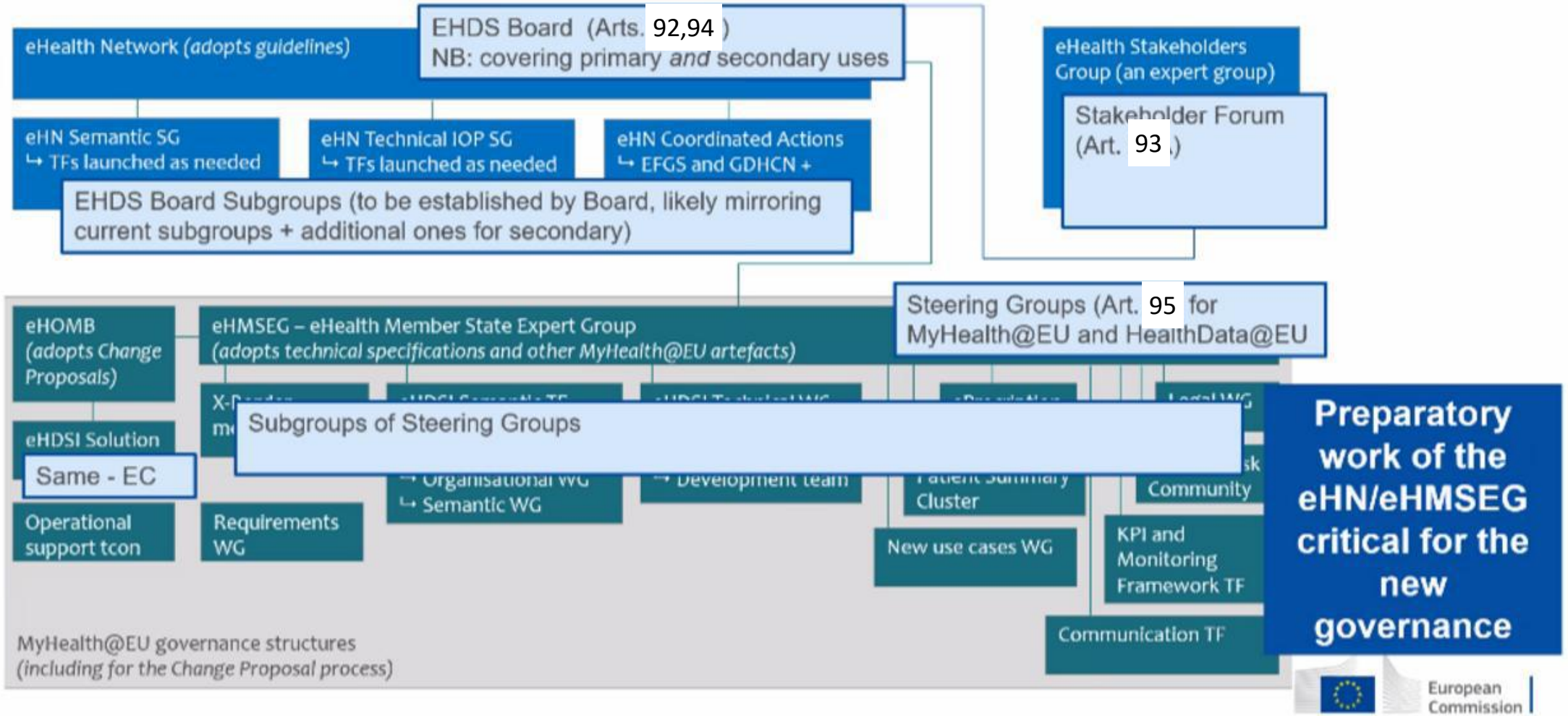
- How would you evaluate the level of maturity of RWD in Greece ?
  - Data availability ?
  - Data quality ?
  - Collaboration readiness / openness between stakeholders ?
- What is the most important application domain for RWD in industry?
- Given the maturity of the data ecosystem what are some of the biggest challenges to reuse data?
- What should the EHDS deliver to reduce some of these challenges?

What would meaningful, societally-valuable use of cancer data look like in Greece

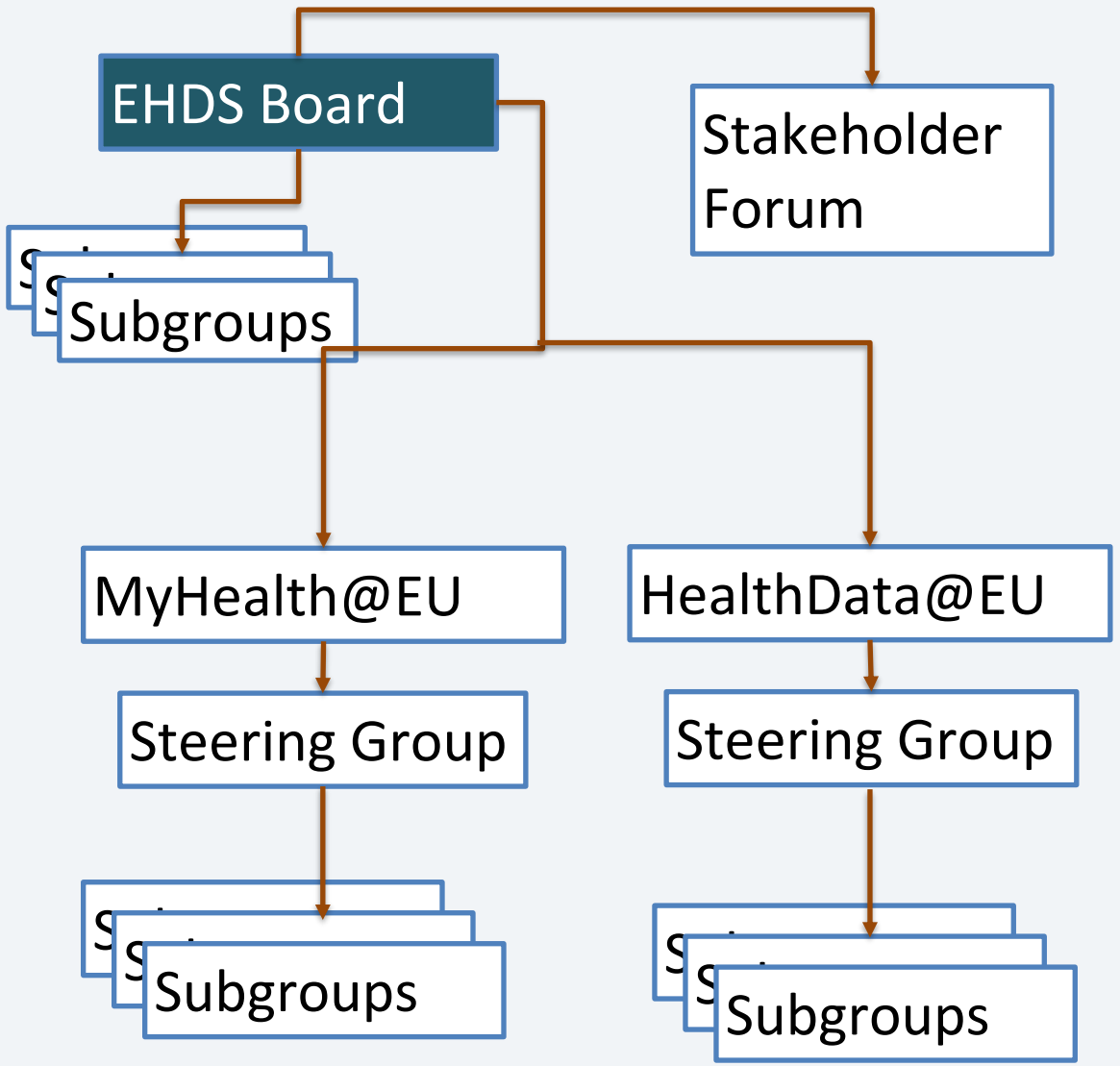
The European Institute for Innovation through Health Data

My Data, Our Health
2nd July 2025, Athens

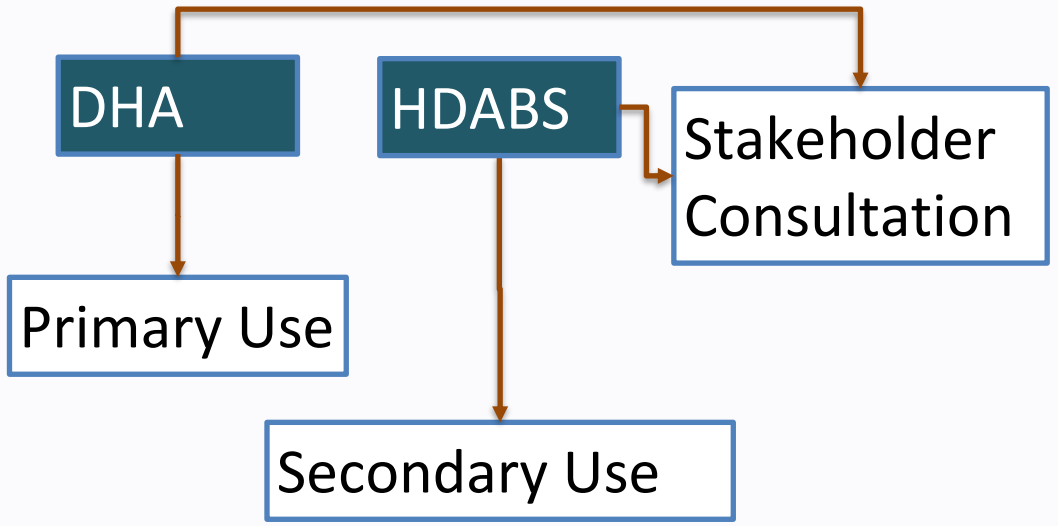
Transition to the new governance bodies



EHDS Governance



National Governance



What would a successful national Stakeholder Forum look like for Greece?