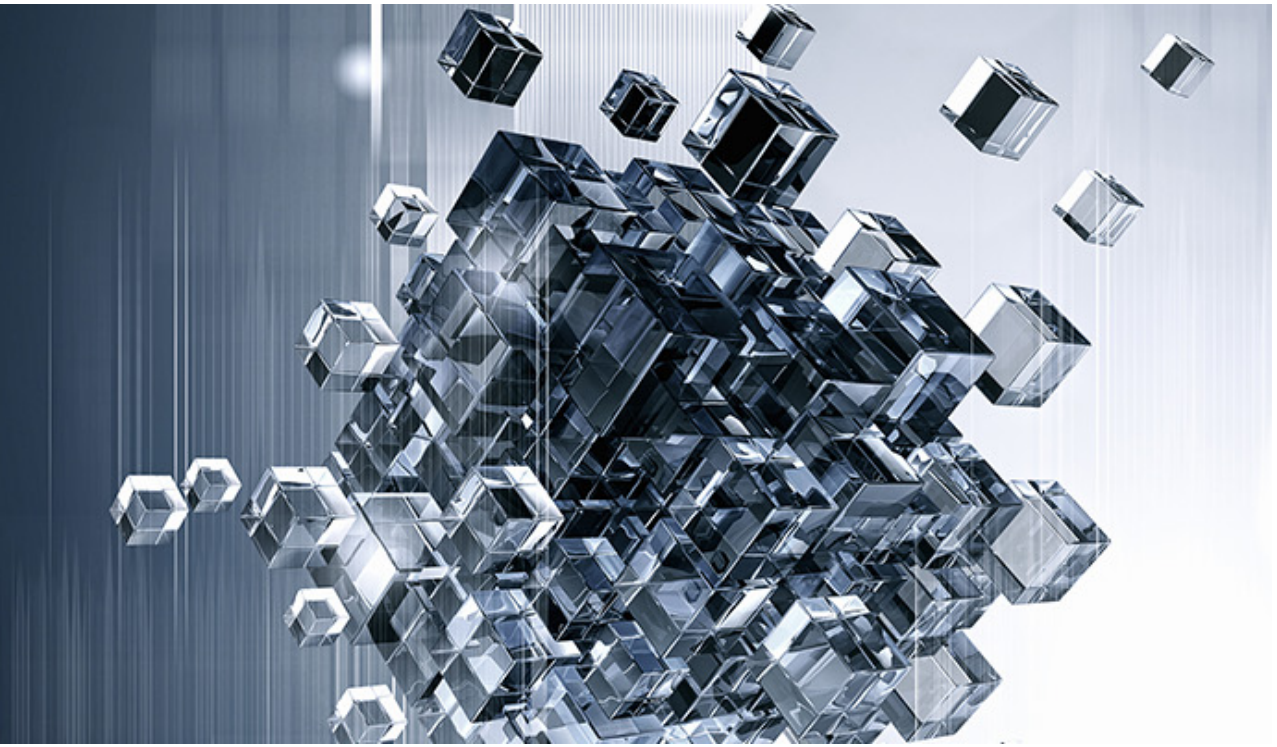
Health data drives innovation

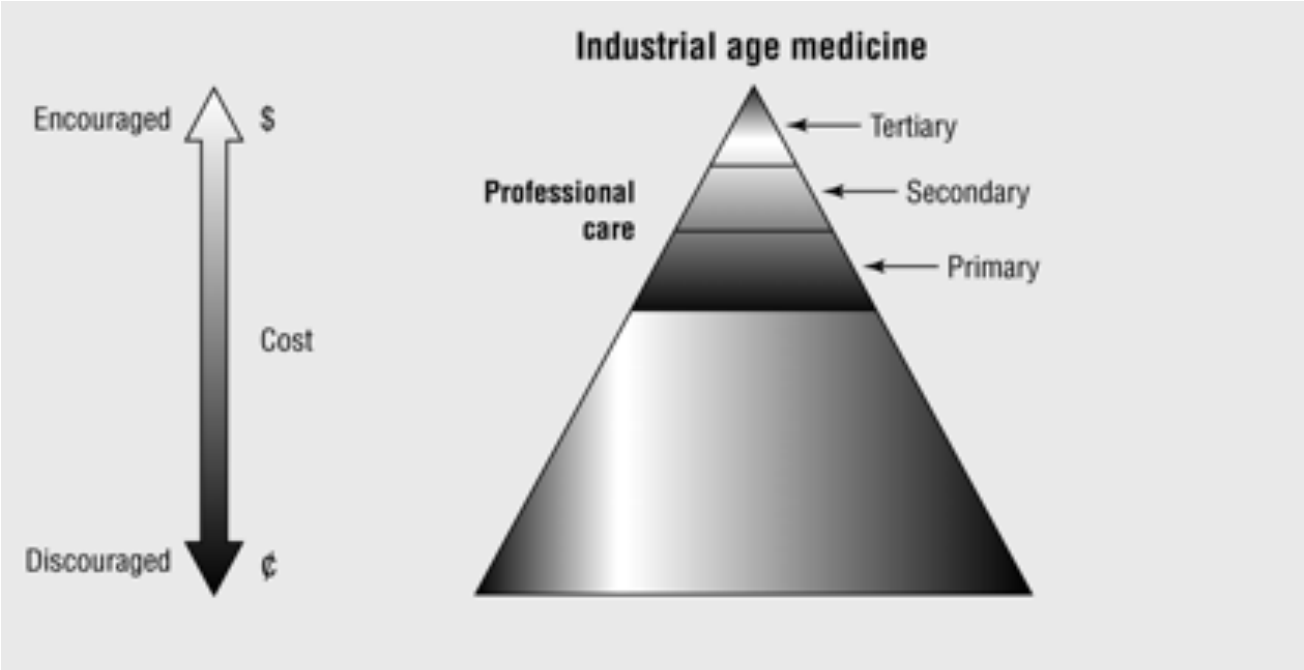
MIE 2023
Sharing is caring



Caring through data: scaling up the opportunities to learn how we can improve health and care

Professor Dipak Kalra
President

The European Institute for Innovation through Health Data



Jennings et al. Changing Health Care: Creating Tomorrow's Winning Health Enterprises Today. 1997

I would like to…

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

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

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.

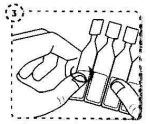
3. How to use Fixapost

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.

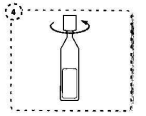
Contact lens wearers
If you wear contact lenses, you should remove them before using Fixapost. After using Fixapost you should wait 15 minutes before putting your contact lenses back in.

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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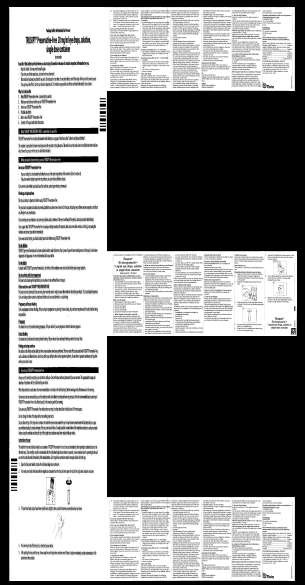
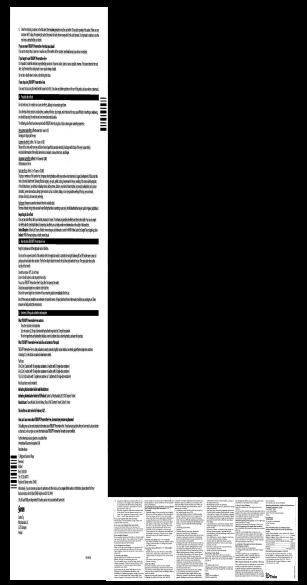
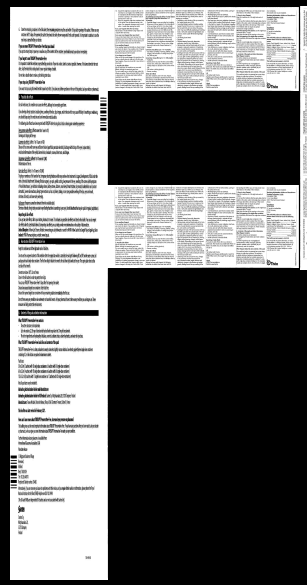





Gravitate Health

Gravitate-Health

Empowering and Equipping Europeans with Health Information for Active, Personal Health Management and Adherence to Treatment

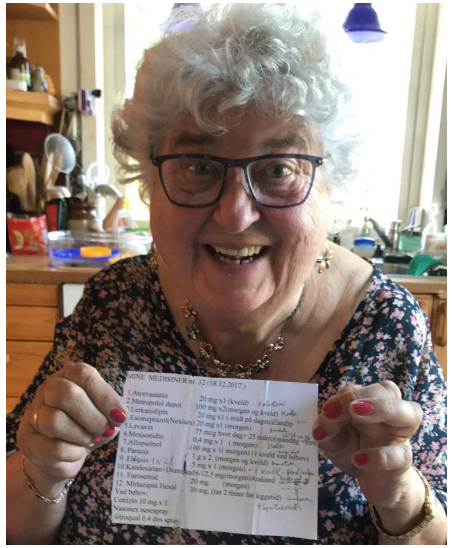
innovative medicines initiative

efpia

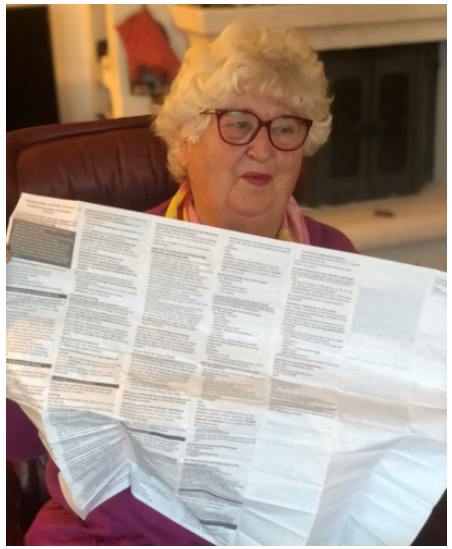
Datapharm

Gravitate-Health public-private partnership

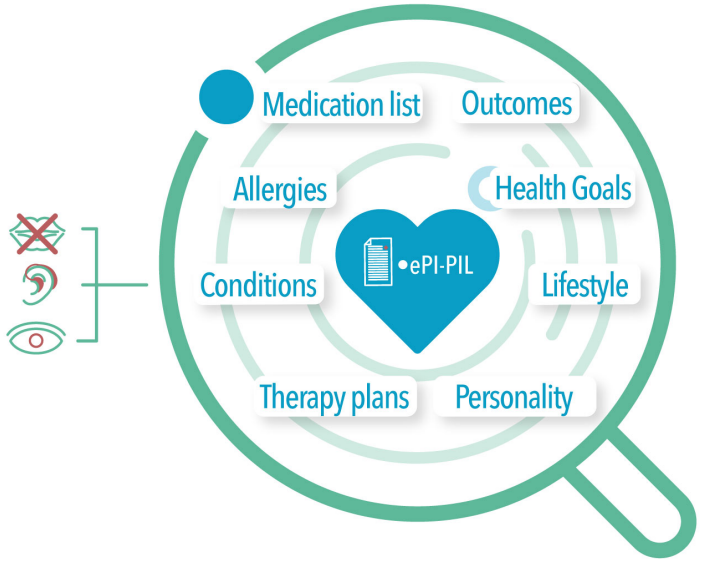
Maria and her medicines



Picture: Line H. Linstad, NSE



Picture: Hanne Bjertnes, UiO



Electronic Health Records (EHR)

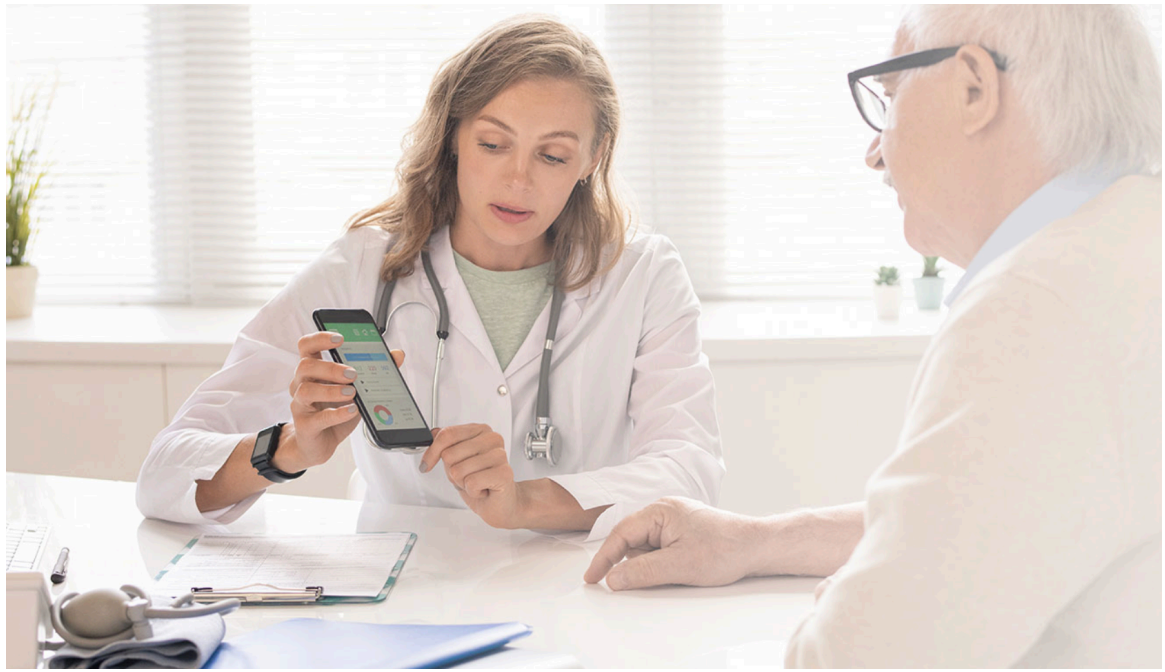
Regulator-approved electronic product information (ePI)

Plus: Health education materials

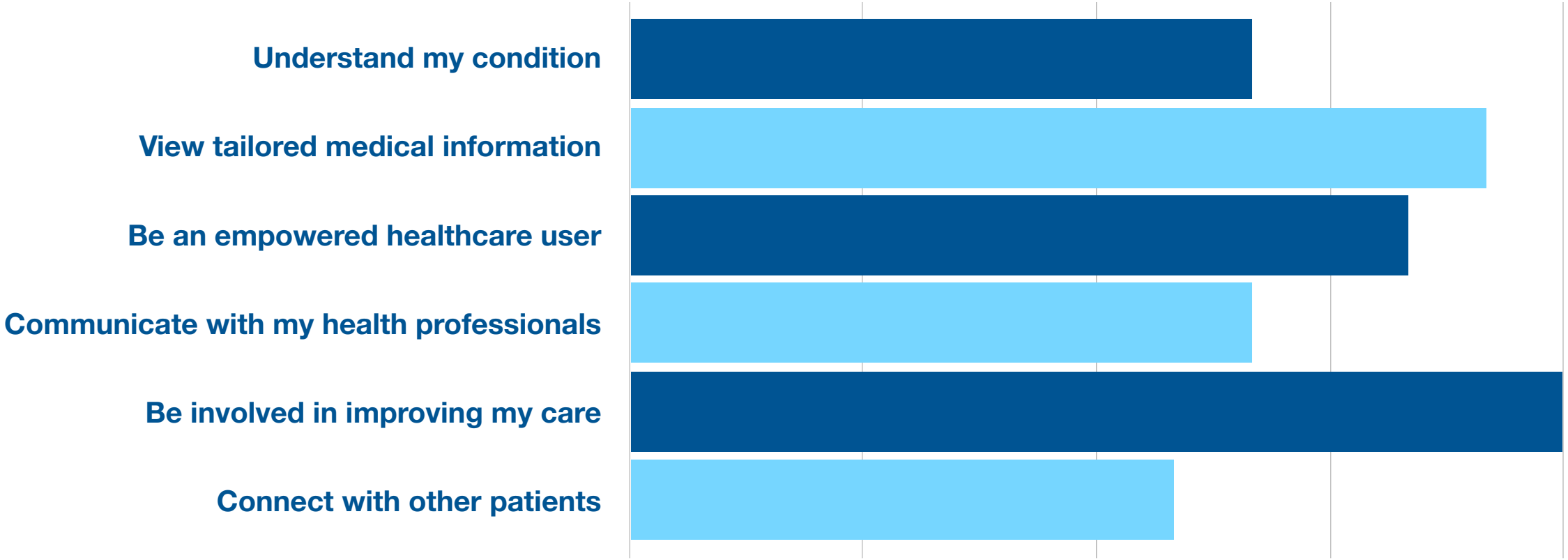
How can we apply an open access digital platform with trusted Digital health Information to transform the way patients access and understand health information, and apply this in personal health for adherence to treatment, risk minimization and quality of life ?

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



I would like to…



H2O - The Health Outcomes Observatory: A Public Private Partnership

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement Nº 945345-2.
This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and Trial Nation and JDRF.

H_2O | Aim

To improve the quality of care for patients
by creating **‘health outcomes observatories’**
that will collect standardised health data
in an ethical and socially responsible way.

Development of outcomes sets via Delphi, with patient engagement

Breast Cancer Research and Treatment (2023) 198:265–281
https://doi.org/10.1007/s10549-022-06827-6

EPIDEMIOLOGY

International development of a patient-for assessing health-related quality of li patients

K. M. de Ligt[1] · B. H. de Rooij[2,3] · E. Hedayati[4,5] · M. M. Karste
L. Travado[10] · F. Cardoso[10] · E. Lopez[11] · N. Carney[12] · Y. Weng
M. D. L. Sousa Fialho[17] · Y. Seidler[18] · T. A. Stamm[18,19] · L. B. K
Innovative Medicines Initiative - Health Outcomes Observa

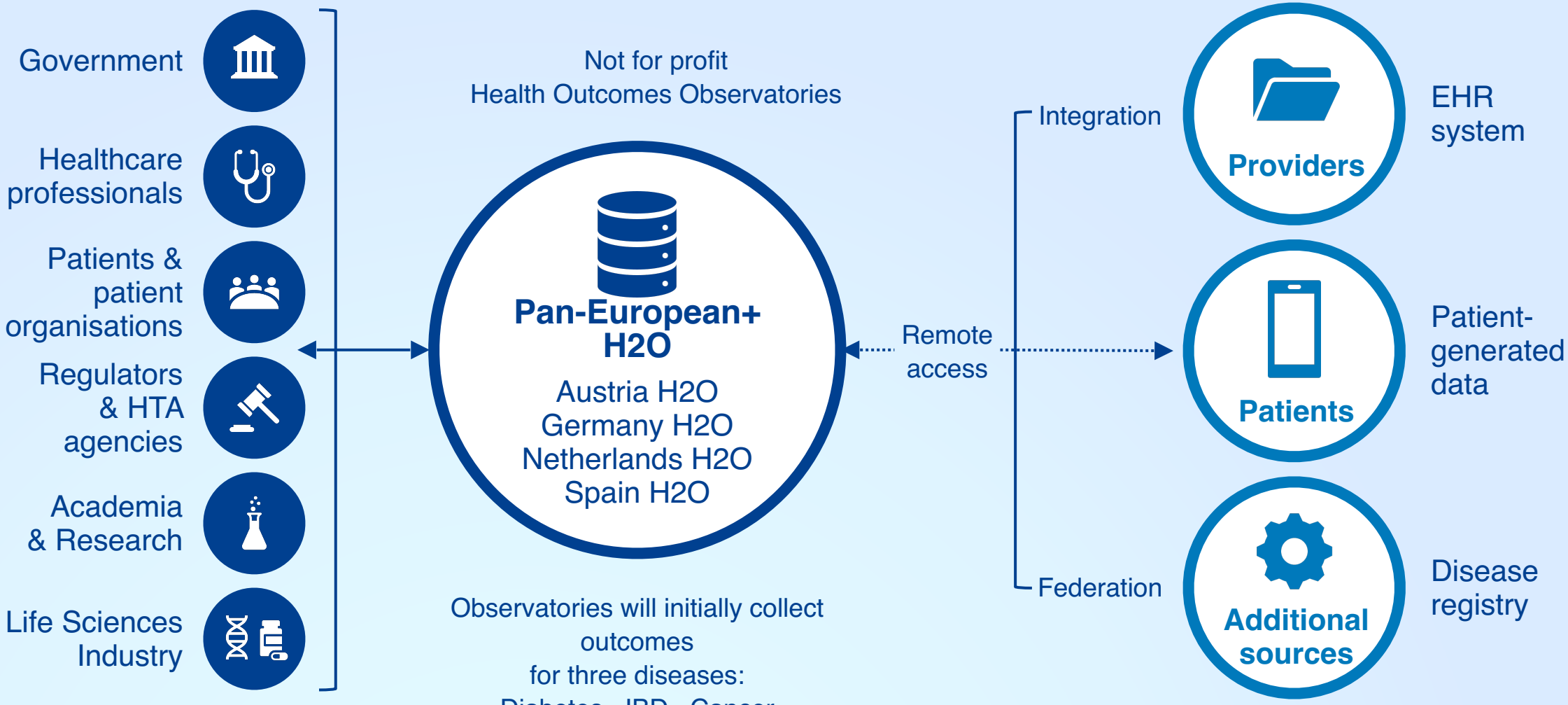
Final Delphi consensus
= 101 variables

Table 1 Relevance scores for each preliminary outcome per methodological round

	Expert group meetings	Modified Delphi consensus procedure								Final consensus meeting
		Round 1				Round 2				
	% response 7-9 ('highly relevant')									Included
Stakeholder group	EG	Patients	HCPs/ academics	Industry	HA/HR	Patients	HCPs/ academics	Industry	HA/HR	EG
Number of participants (n (%))	17 (100)	45 (100)	64 (100)	28 (100)	4 (100)	43 (96)	56 (88)	20 (71)	4 (100)	17 (100)
Clinical variables: tumour and treatment characteristics of primary tumour*										
Laterality	62 (included following discussion in EG)	46	33	65	33	44	32	56	50	Excluded
Mutation status predisposing BC	Rephrased to: Result of clinical genetic tests	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded
Date of diagnosis	92	61	66	82	66	70	71	78	50	Included
Type of breast cancer	92	80	90	92	66	93	95	95	50	Included
Tumour grade	85	82	78	90	66	97	91	95	50	Included
Clinical cancer stage	85	78	88	97	66	92	89	100	50	Included
Pathological cancer stage	75	76	87	90	66	90	87	94	50	Included
Size of tumour	69 (included following discussion in EG)	84	75	82	66	93	85	90	50	Included
Number of lymph nodes removed	31(included following discussion in EG)	84	66	66	33	89	74	83	0	Included
Number of lymph nodes involved	62 (included following discussion in EG)	81	80	70	67	95	83	83	50	Included
Estrogen receptor status	100	89	89	92	50	95	91	95	0	Included
Progesteron receptor status	92	82	86	85	50	95	85	83	0	Included
HER-2-status	100	91	91	96	66	97	91	95	50	Included

ICHOM CERTIFIED

H_2O | First European scale network for health outcomes data



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

Patients often want to share!

Learn about health conditions, treatment options

Track health state

Set personal goals

Compare with others

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

The spectrum of data use: from care to research

Individual level health data

EHR systems, apps, sensors, genomics, Clinical Decision Support, AI

Used for:

- Health status monitoring
- Continuity of care (including the patient and caregivers)
- Care pathway tracking, clinical workflow management
- Real-time feedback and guidance to patients and clinicians
- Personalised medicine
- Disease interception, prevention and wellness
- Healthcare provider reimbursement

Population level health data

EHR systems, regional & national eHealth infrastructures

Reused for:

- Healthcare provider performance and planning
- Quality and safety, care pathway optimisation
- Medical device and algorithm refinement
- Pharmacovigilance
- Public health surveillance
- Public health strategy
- Health services and resource planning

Big health data

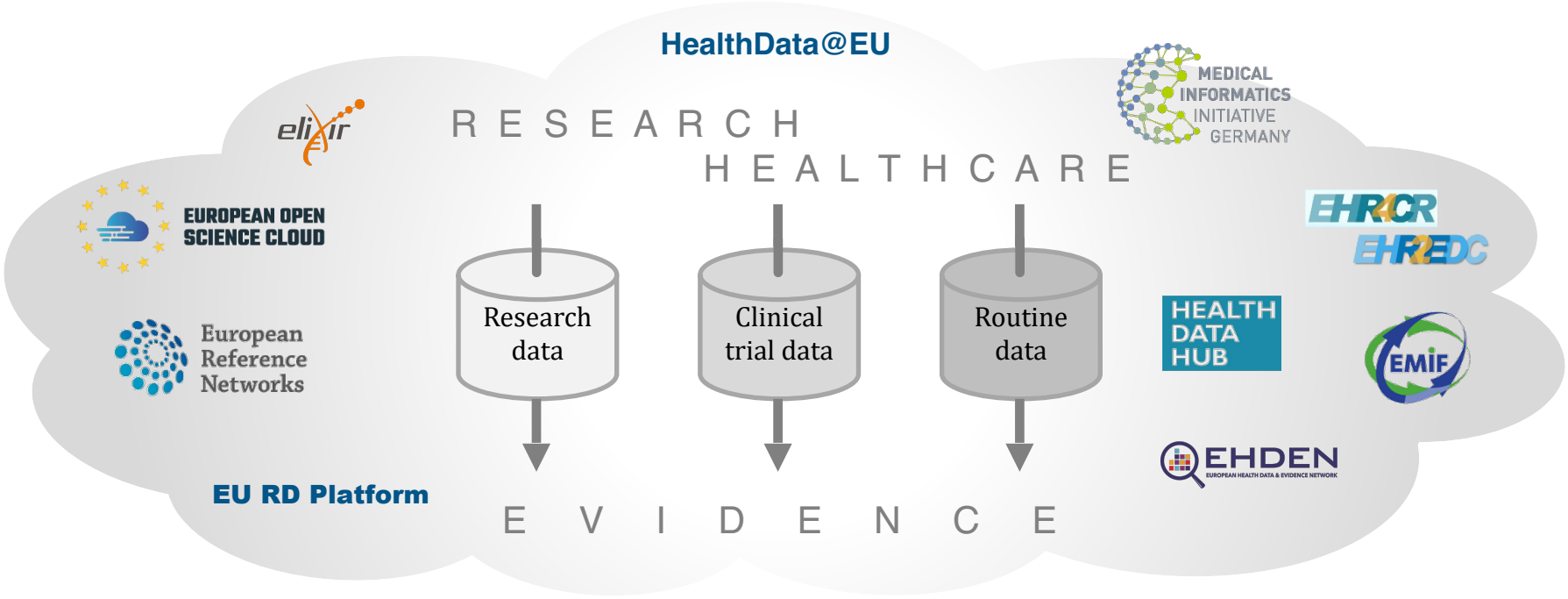
national & international research infrastructures, federated query platforms + cross-sectoral services

Reused for:

- Epidemiology
- Digital innovation: devices, sensors, apps
- AI development
- Personalised medicine and bio-marker research
- Diagnostics development
- Drug development
- Disease understanding and stratification

Big health data sharing initiatives

- Myriad of initiatives to share health data across jurisdictional, institutional and domain borders:
  - Sharing data for cross-border care or for research
- Emerging paradigm for analysing personally-identifiable health data:
  - federated infrastructure model: network of repositories with an overarching governance and interoperability layer



Proposal for a Regulation on the European Health Data Space

It sets out rules, common standards, infrastructures and a governance framework for the use of electronic health data for healthcare, research, innovation and policy making

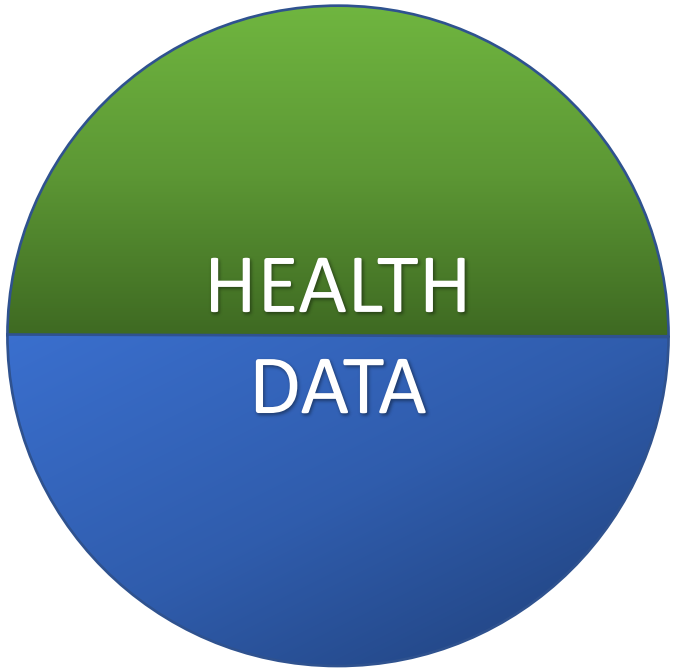
Empower individuals to access and control their personal health data

Ensure a consistent framework for the use of individuals' health data for research, innovation, policy-making and regulatory activities

Unleash the data economy by fostering a genuine single market for digital health services and products (EHR systems)

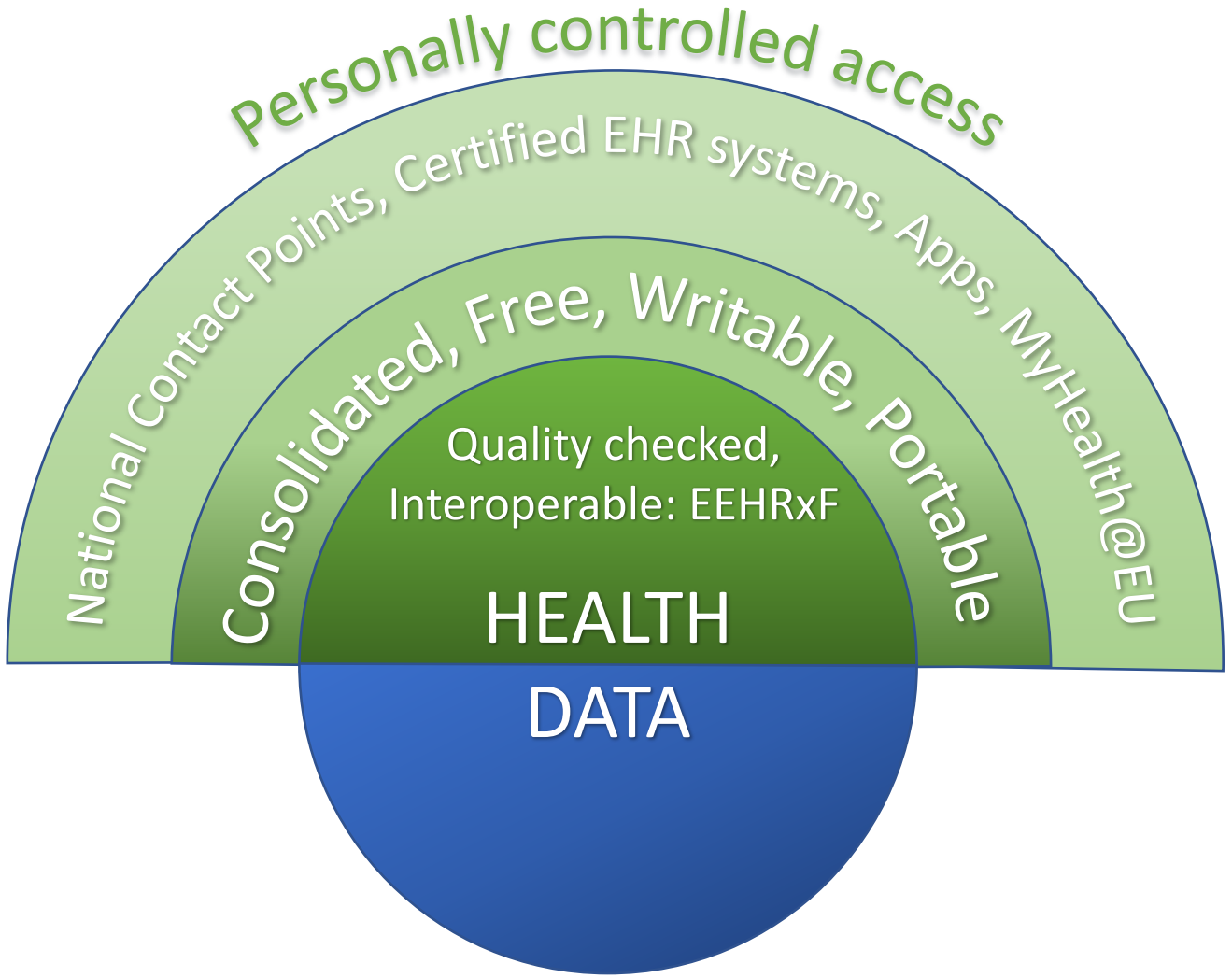
European Commission

Primary Use
For health, care, wellness



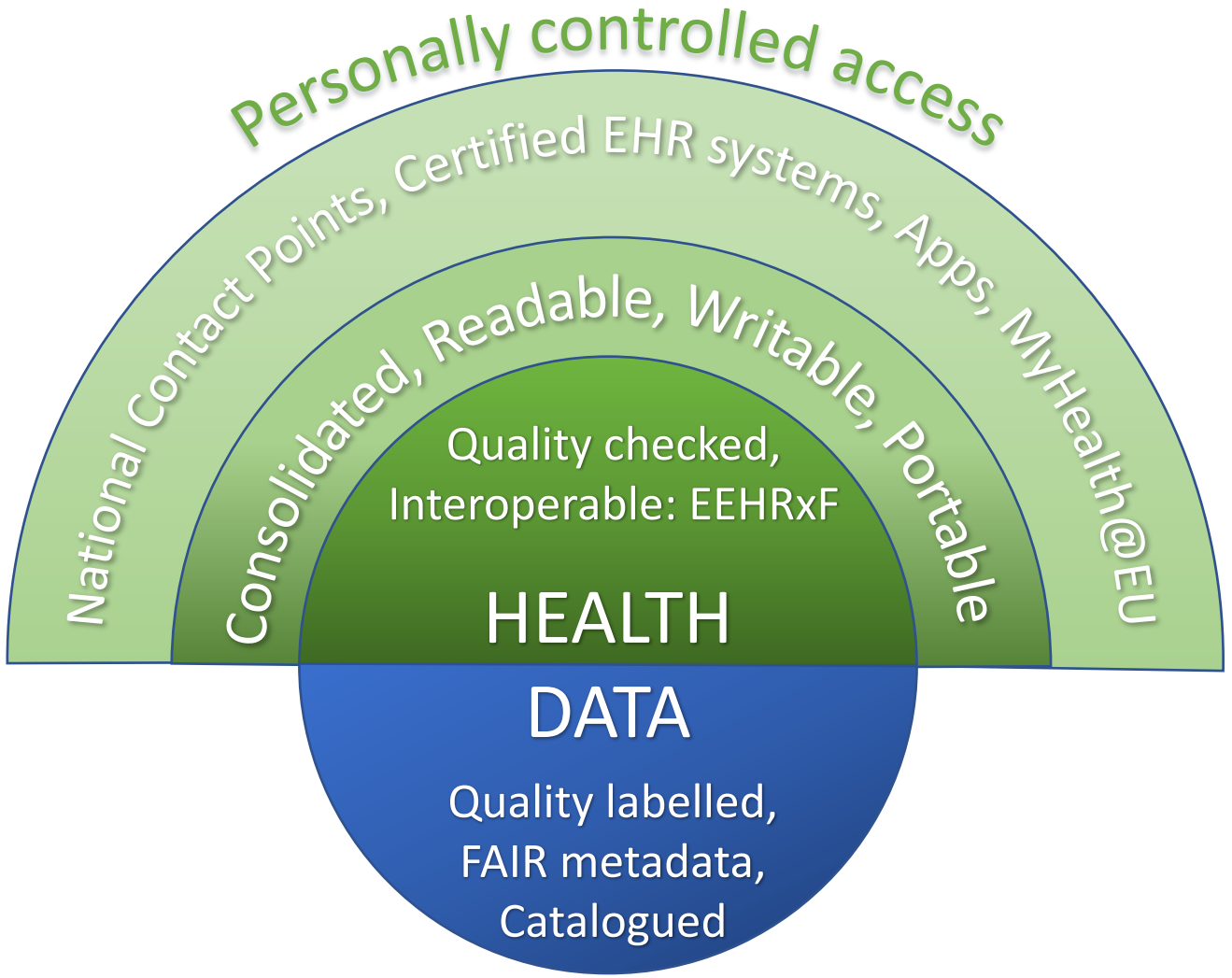
Secondary Use
For research and strategy

Primary Use
For health, care, wellness



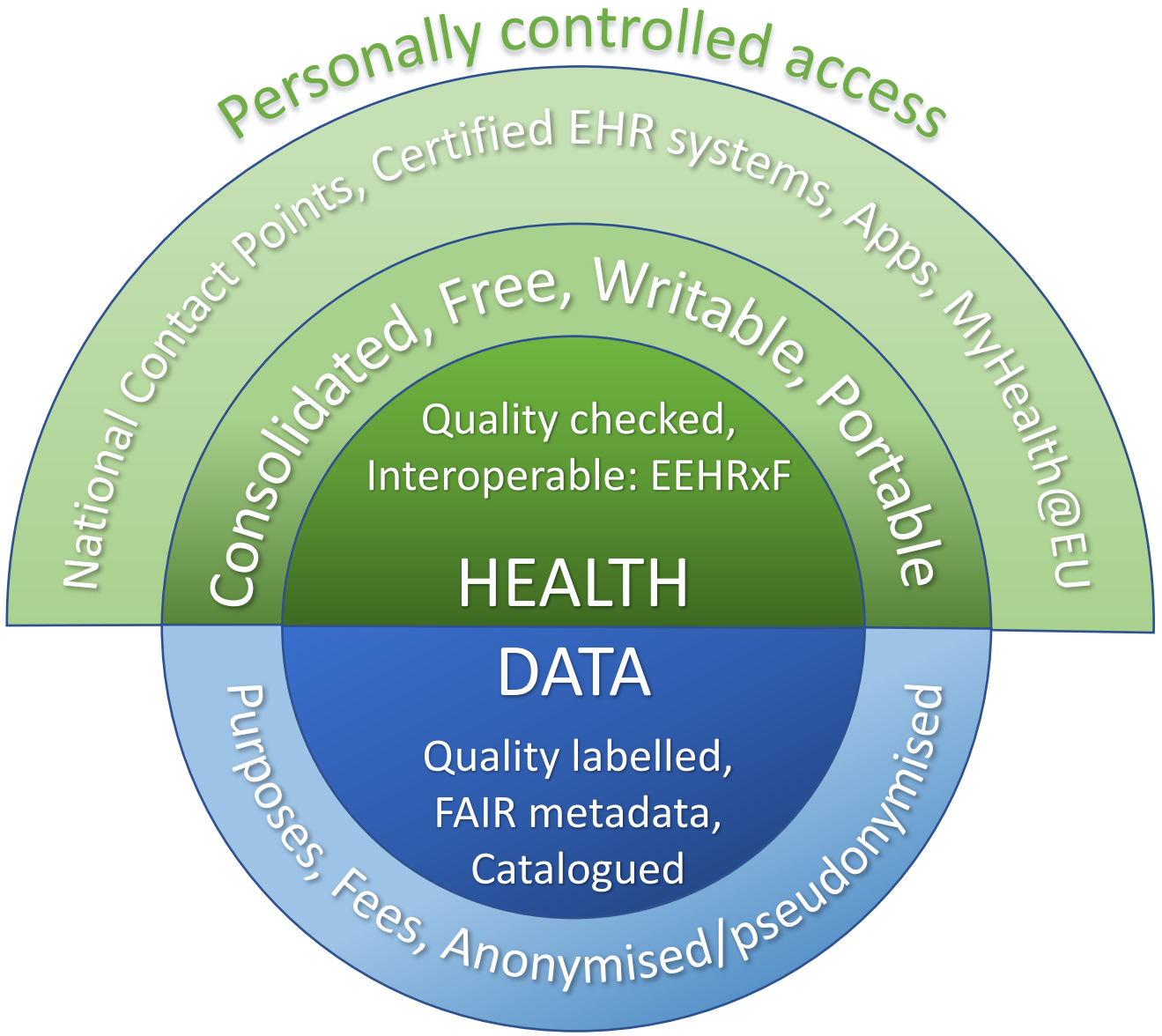
Secondary Use
For research and strategy

Primary Use
For health, care, wellness



Secondary Use
For research and strategy

Primary Use
For health, care, wellness

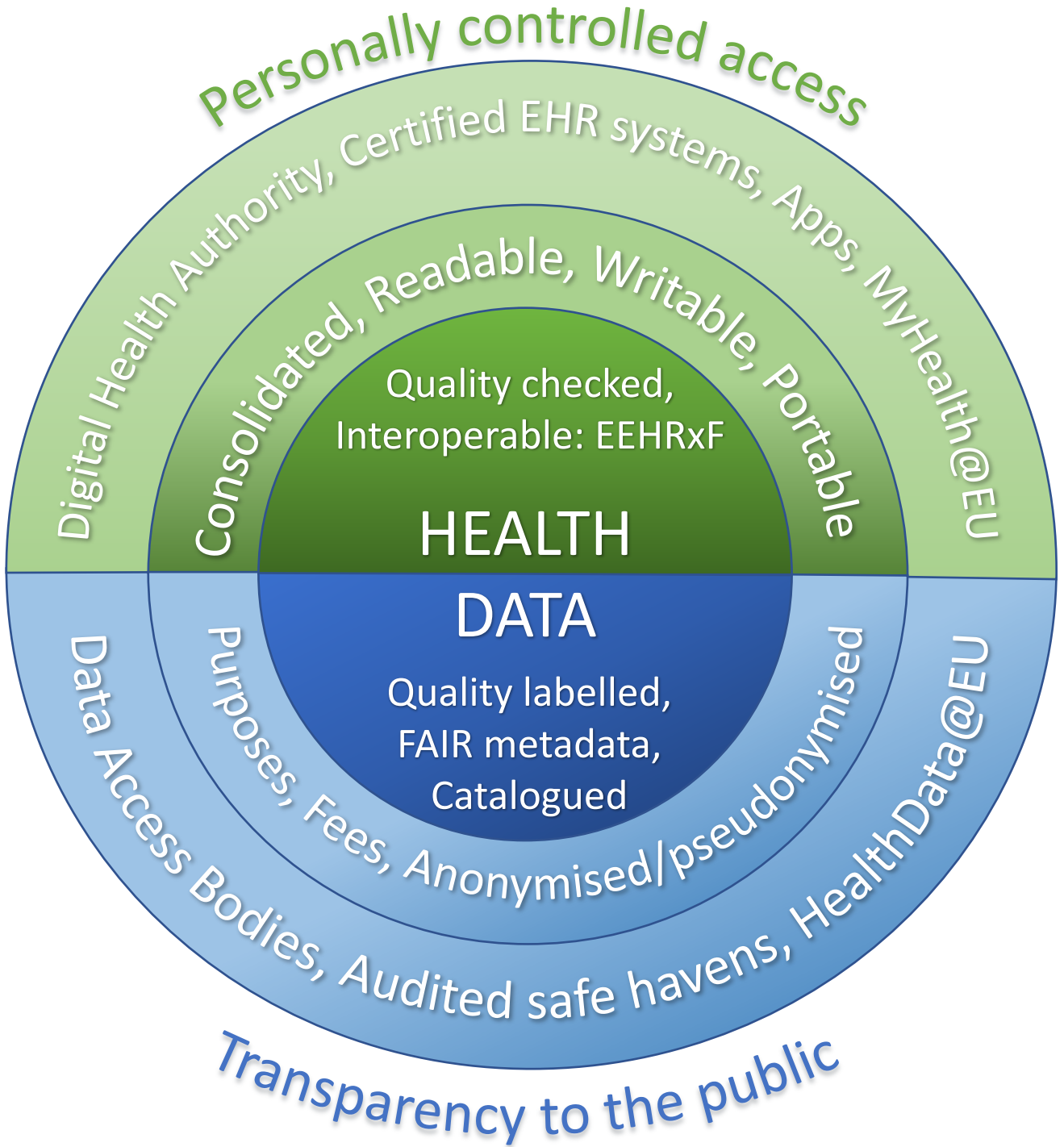


Secondary Use
For research and strategy

Primary Use
For health, care, wellness

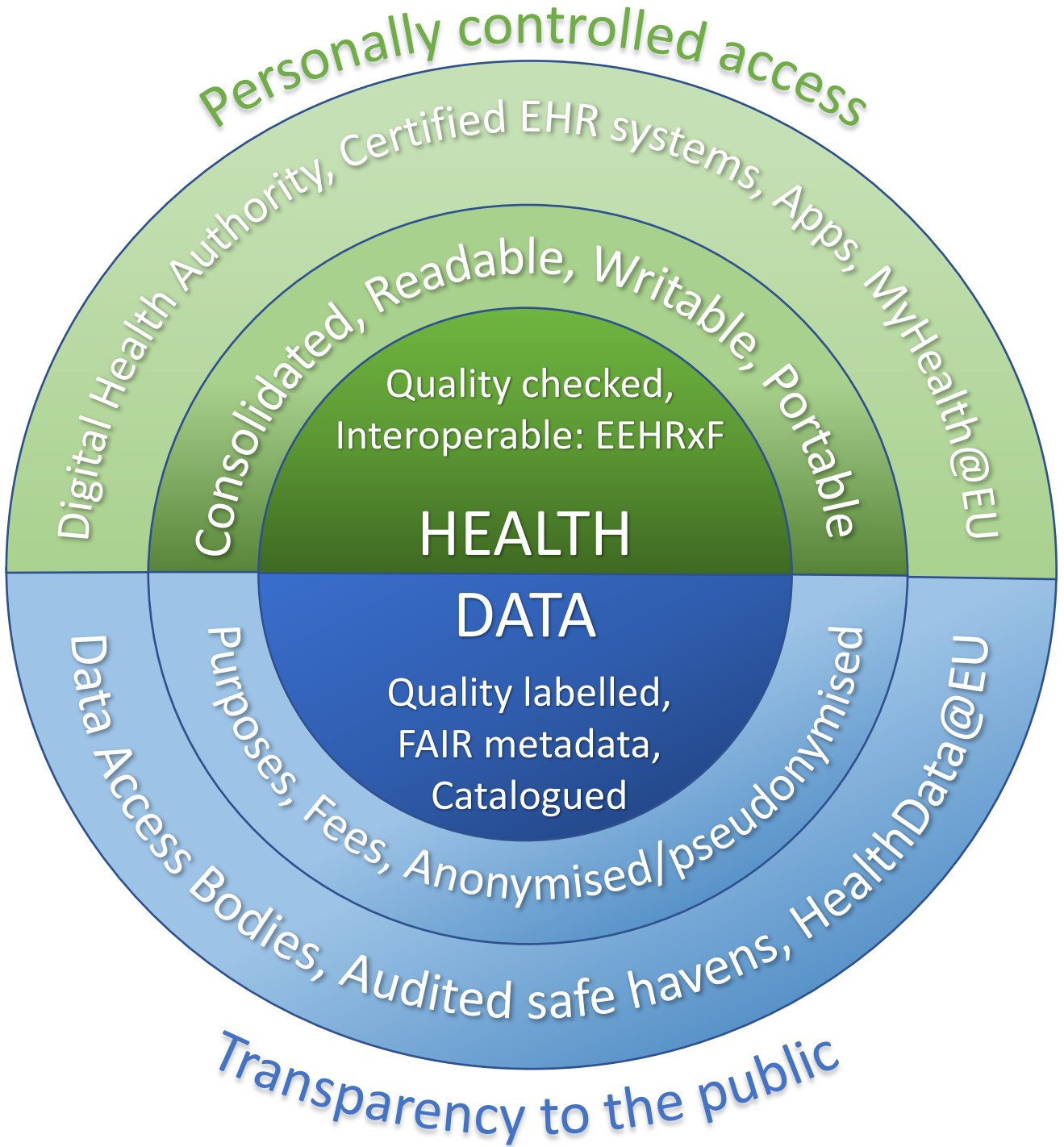
Secondary Use
For research and strategy

Primary Use
For health, care, wellness



Secondary Use
For research and strategy

Primary Use
For health, care, wellness



Secondary Use
For research and strategy

The challenge with trusting:

Individual level health data	Population level health data	Big health data
EHR systems, apps, sensors, genomics, Clinical Decision Support, AI guidance	EHR systems, regional & national eHealth infrastructures	national & international (federated) research infrastructures,
Used for direct care, provider level quality and reimbursement	Used for public health programmes, health system strategy	Used for drug development, AI and medical devices, unmet treatment needs

Decreasing public understanding of why and how data are used

Increasingly unfamiliar data users

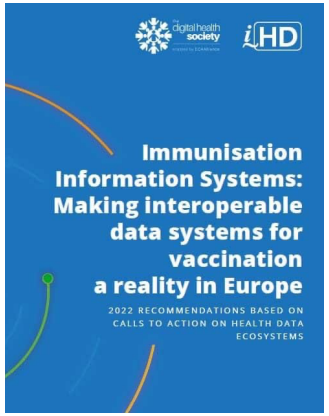
Increasing time from data use to demonstrated value

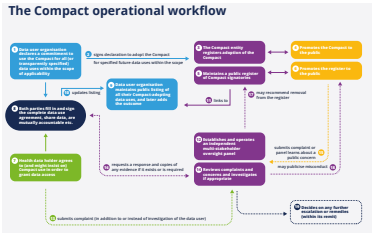
Increasing distance of data results from the patient

Perceived lessening choice and greater cybersecurity risk = harder to trust

Consulting with stakeholders on success factors for the EHDS

DigitalHealth Europe project:
EHDS: Policy White Paper, industry consultation, patient and citizen consultations





Multi-stakeholder consensus events and reports 2020-23, joint i~HD and DHS, sponsored by MS, J&J and MSD

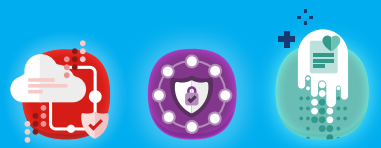
Recommendations to Data Access Bodies

Proposal for a Societal Compact

Defining data access policies and rules	Making data access decisions	Publicising the outcomes of health data access
Ensure that the policies and rules developed for data access decision making adequately reflect public preferences and optimally balance differing public viewpoints	Provide public information about the uses being made of health data, to a meaningful but practical level of granularity and specificity	Inform all stakeholders, especially the public, about the societal benefits intended and later achieved through each granted data access request
Be transparent, to all stakeholders and to the public, about the principles and rules that will be applied when evaluating data access requests	Be as transparent as is legally permissible about declined data access requests, data breaches or infringements of policies and codes of conduct, and how these have been handled	Periodically review the effectiveness and successful outcomes from implementing the data access policies and rules, and revise them to improve the trustworthy value from health data for society
Specify and publish the data processing conduct expected from all data users, including how this will be monitored and enforced		

Proposal for a Societal Compact for the secondary use of health data

2023 RECOMMENDATIONS BASED ON CALLS TO ACTION ON HEALTH DATA ECOSYSTEMS



A societal compact (or social contract)

- A voluntary agreement between a range of stakeholders
- who co-operate to achieve social benefits by granting access to and reuse of health data
- The Compact
  - aims to provide an assurance to all stakeholders in the health data ecosystem, especially the public
  - that organisations and individuals reuse health data in legal, ethical and secure ways
  - and in society's interests

Ethical principles for health data reuse

1 **Health and health related data must only be reused for purposes that aim to directly result in, or contribute to bringing, benefits to society in terms of improved opportunities for better health and care.**

2 **Health and health related data must never be reused for purposes that are unethical, violate human rights, will disadvantage or are very likely to disadvantage individuals or groups of individuals, or will exclusively further individual or organisational interests without bringing benefits to some parts of society.**

3 **The reuses of health and health related data must always safeguard the privacy of individuals whose data are being reused, by complying with all applicable data protection laws (such as the EU GDPR), by using aggregated or anonymised data whenever possible (but balanced against benefits which may be achieved by using identifiable or pseudonymised data) and by adopting robust information security measures.**

Ethical principles for health data reuse

4 The reuses of health data must be respectful to the holders of the data being used, and adhere to data use terms agreed with the data holders including the purposes for which their data may be reused.

5 The results from reusing health and health related data should be published, or shared in some other way unless the results are subject to commercial use for products and services, in which case those products and services should be available to all possible adopters on fair terms such as fair pricing.

6 Organisations that reuse health and health related data must make every effort to be as transparent as possible to the public about their use of health data and the outcomes of each data use.

7 Bodies that make decisions to permit data access must ensure that these principles are upheld when defining decision making rules and be transparent to the public about those rules, the data access decisions that they make and the societal benefits that those data reuses have enabled.

Purposes for which EHDS will permit secondary health data use

a) activities for reasons of **public interest in the area of public and occupational health**, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices

b) to support **public sector bodies** or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates

c) to produce national, multi-national and Union level official **statistics related to health or care sectors**

d) **education or teaching** activities in health or care sectors

e) **scientific research** related to health or care sectors

f) development and **innovation activities for products or services contributing to public health or social security**, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices

g) **training, testing and evaluating of algorithms**, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices

h) **providing personalised healthcare** consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons

The Compact includes examples of research, to illustrate purpose e)

Prohibited secondary uses of health data

a) taking decisions detrimental to a natural person based on their electronic health data; in order to qualify as "decisions", they must produce legal effects or similarly significantly affect those natural persons

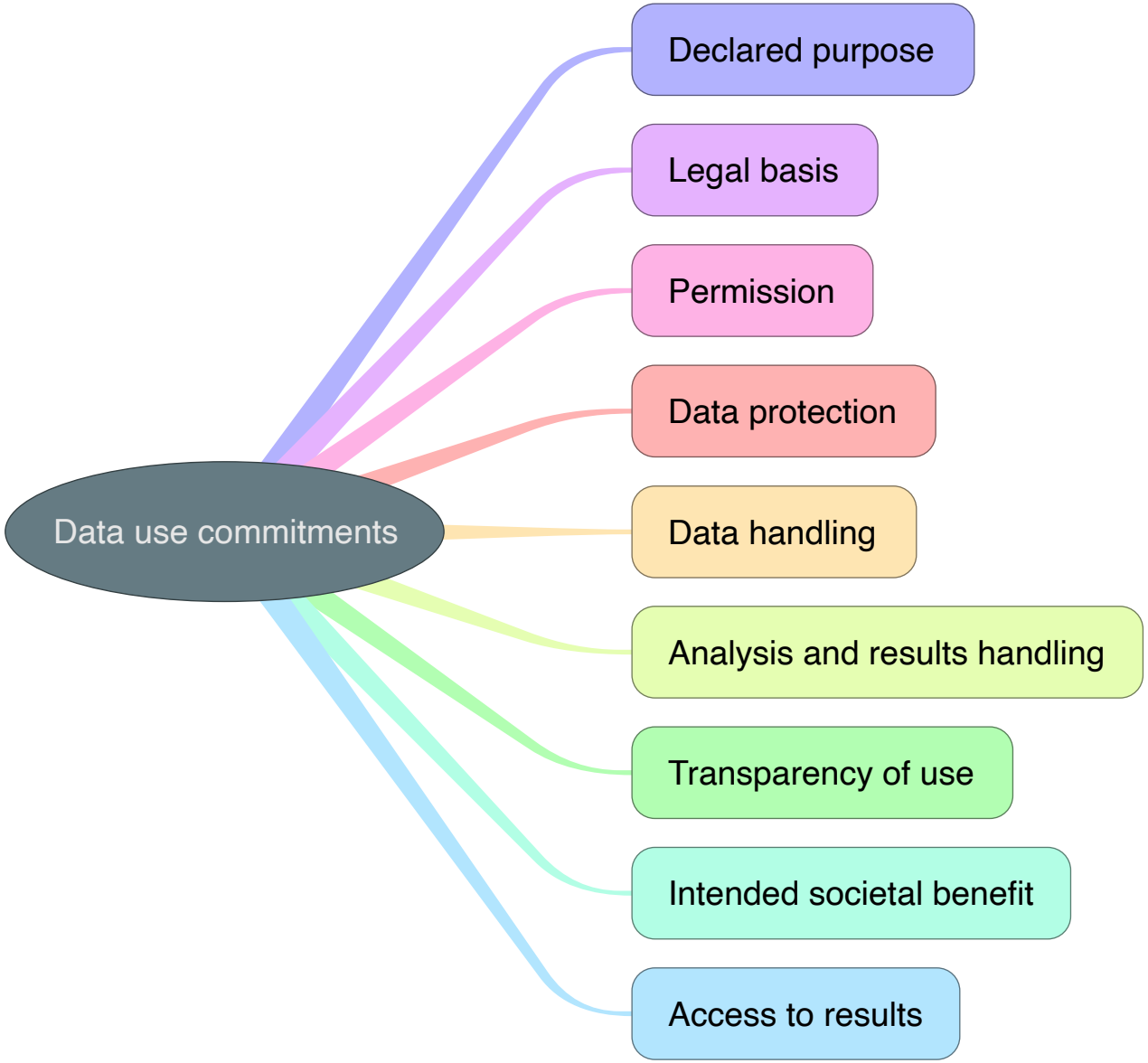
b) taking decisions in relation to a natural person or groups of natural persons to exclude them from the benefit of an insurance contract or to modify their contributions and insurance premiums

c) advertising or marketing activities towards health professionals, organisations in health or natural persons

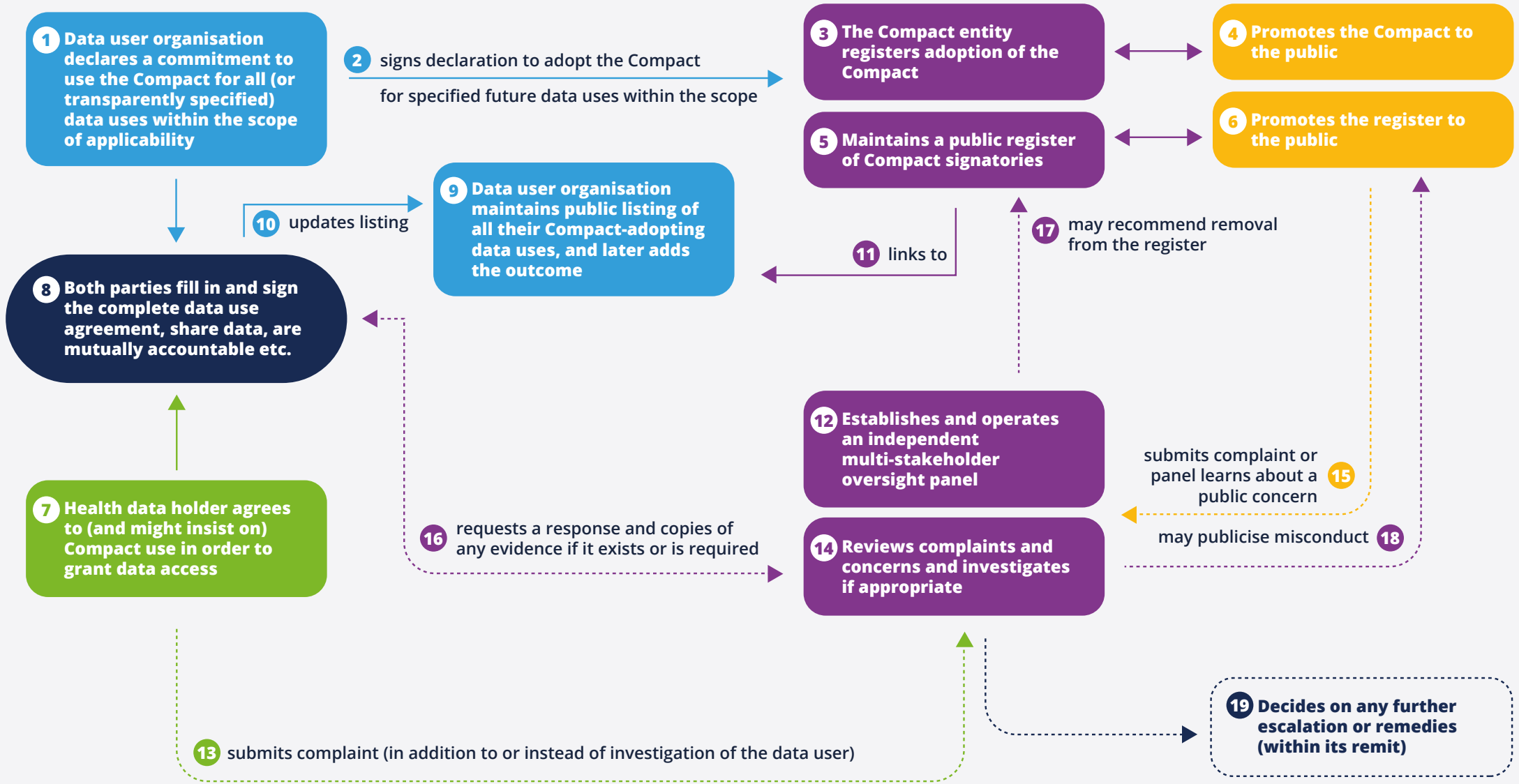
d) providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit

e) developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco products, or goods or services which are designed or modified in such a way that they contravene public order or morality

An organisation adopting this Compact additionally declares that it will not reuse health or health related data for purposes that would **violate the European Convention on Human Rights**.


Data use commitments
Declared purpose
Legal basis
Permission
Data protection
Data handling
Analysis and results handling
Transparency of use
Intended societal benefit
Access to results

The Compact operational workflow



Sharing = caring = trusting

Sharing = caring = trusting

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i~HD Annual Conference 2023
Building Trust in Health Data

29 November – 1 December 2023

Ghent, Belgium

- Improving patient outcomes and medical research through **trusted health data spaces**
- Implementing measures to ensure **medicine safety for patients**
- Sharing **high-value data for care + research**
- Giving **patients the driving seat**

Health Data Quality | Trustworthy ICT Systems | Information Governance - GDPR

Joining the Dots E.C.-funded R&D Projects