

How to Make the Big Data Dream Come True

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The views expressed are those of the presenter and should not be understood or quoted as being made on behalf of the Norwegian Medicines Agency (NoMA), the European Medicines Agency (EMA), its scientific committees or reflecting the position of EUnetHTA21.

A little anecdote on communication...



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My traveling companions were repeatedly talking about the 'mooie rots'



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Well, 'rots' in dutch translates to 'rock' while 'Rotz' (what I though I heard being a German native) is the something very, very different (I spare you the picture)



Take home message 1

- Basic human communication works best if we admit we might not understand, rather than coming to wrong conclusions.

The subtleties of the English language

Anglo-EU Translation Guide

What the British say	What the British mean	What others understand
I hear what you say	I disagree and do not want to discuss it further	He accepts my point of view
With the greatest respect...	I think you are an idiot	He is listening to me
That's not bad	That's good	That's poor
That is a very brave proposal	You are insane	He thinks I have courage
Quite good	A bit disappointing	Quite good
I would suggest...	Do it or be prepared to justify yourself	Think about the idea, but do what you like
Oh, incidentally/ by the way	The primary purpose of our discussion is...	That is not very important
I was a bit disappointed that	I am annoyed that	It doesn't really matter
Very interesting	That is clearly nonsense	They are impressed
I'll bear it in mind	I've forgotten it already	They will probably do it
I'm sure it's my fault	It's your fault	Why do they think it was their fault?
You must come for dinner	It's not an invitation, I'm just being polite	I will get an invitation soon
I almost agree	I don't agree at all	He's not far from agreement
I only have a few minor comments	Please re-write completely	He has found a few typos
Could we consider some other options	I don't like your idea	They have not yet decided

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Very interesting

• What British say

That's clearly nonsense

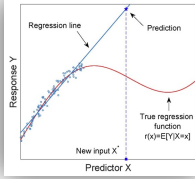
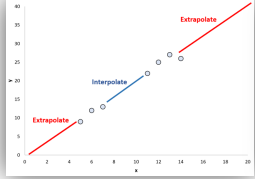
• What they mean

They are impressed

• What others understand

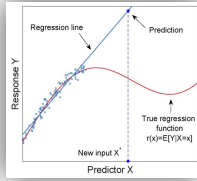
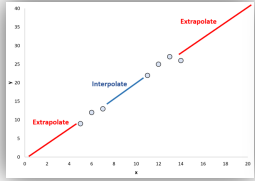
Take home message 2

- Basic human communication works best if we admit we might not understand, rather than coming to wrong conclusions.
- There is no such thing as a 'simple translation'.

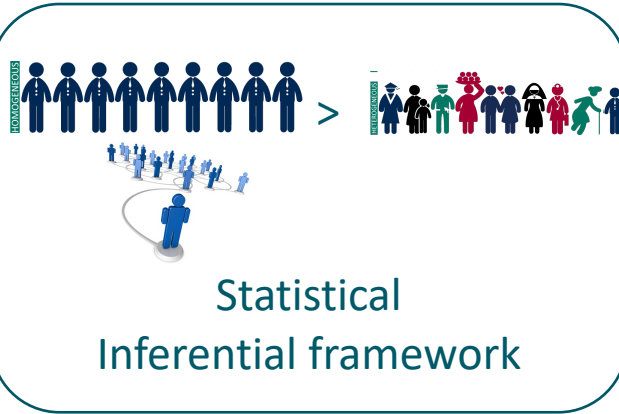


Mathematical

Extrapolation

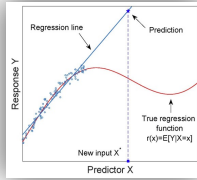
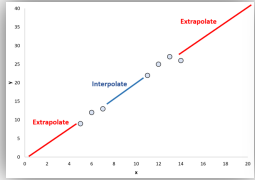


Mathematical

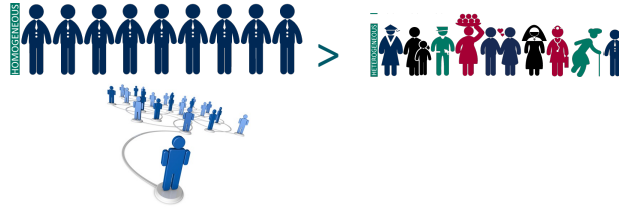


Statistical
Inferential framework

Extrapolation



Mathematical

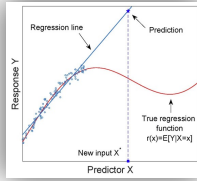
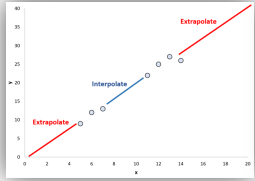


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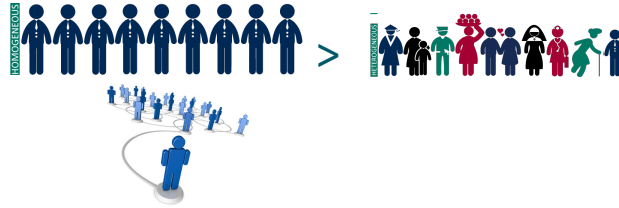


= Generalisation

Extrapolation



Mathematical

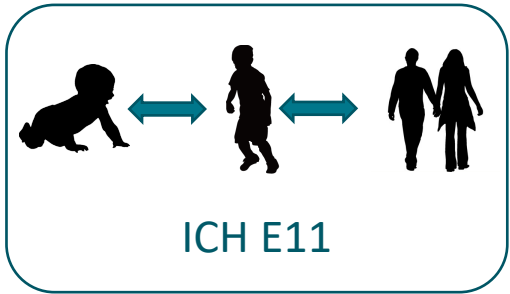


Statistical
Inferential framework

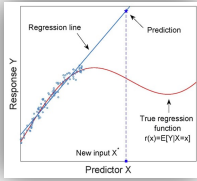
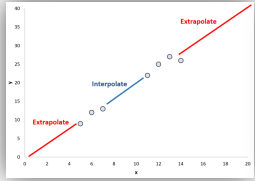


= Generalisation

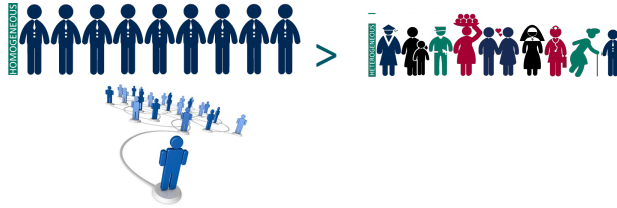
Extrapolation



ICH E11



Mathematical



Statistical
Inferential framework



= Generalisation

Extrapolation

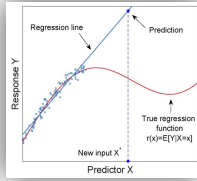
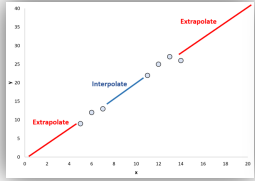


HTA

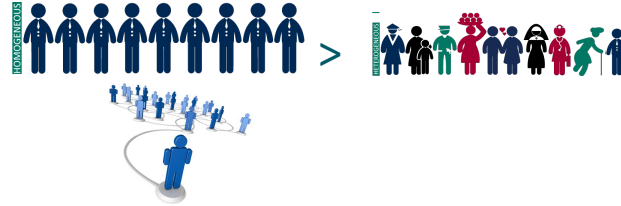
Relative effectiveness



ICH E11



Mathematical

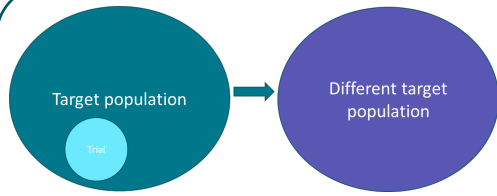


Statistical
Inferential framework

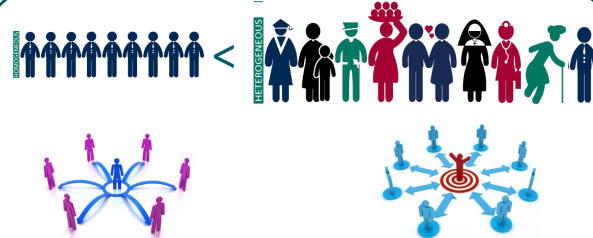


= Generalisation

Extrapolation



= Transportability



HTA

Relative effectiveness



ICH E11

Take home message 3

- Basic human communication works best if we admit we might not understand, rather than coming to wrong conclusions.
- There is no such thing as a 'simple translation'.
- 'Meaning' is context dependent....

Say what you mean is a good start

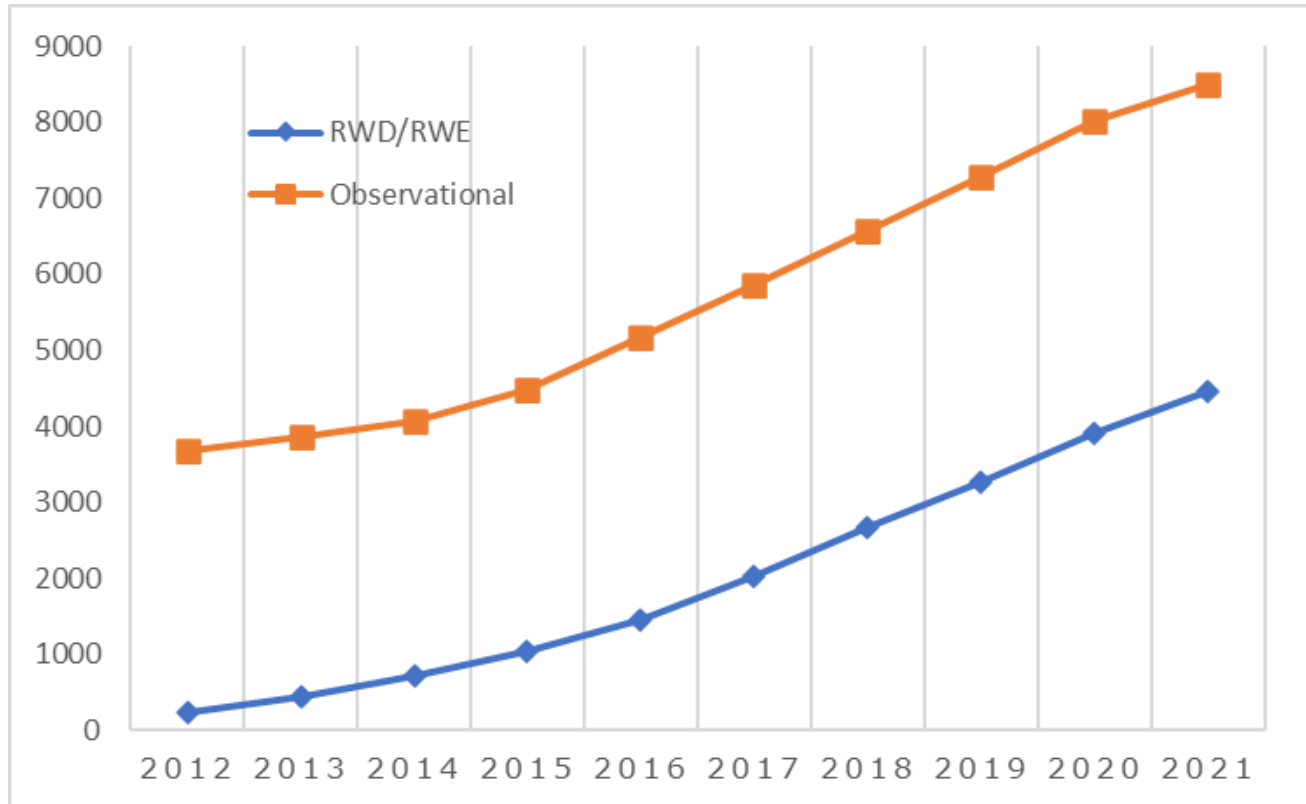
- “Then you should say what you mean,” the March Hare went on. “I do,” Alice hastily replied; “at least — at least I mean what I say — that's the same thing, you know.” “Not the same thing a bit!” said the Hatter. “You might just as well say that “I see what I eat” is the same thing as “I eat what I see”!”



Back to the topic, what are we talking about



Number of publications mentioning buzz words



Take home message 4

- Basic human communication works best if we admit we might not understand, rather than coming to wrong conclusions.
- There is no such thing as a 'simple translation'.
- 'Meaning' is context dependent....
- When it comes to RWD/RWE, I am afraid we don't know what we talk about per se.

Communication is not just a human thing

- Give a definition at the start of any discussion!
- There is a difference between
 - the 'wish' to use something,
 - the 'need' to use something
 - the 'ability' to use something
- There is a difference between
 - Having a lot of data
 - Having a lot of 'good' data
 - Having a lot of 'fit for purpose' data
 - Having a lot of

Take home message 5

- Basic human communication works best if we admit we might not understand, rather than coming to wrong conclusions.
- There is no such thing as a 'simple translation'.
- 'Meaning' is context dependent....
- When it comes to RWD/RWE I am afraid we don't know what we talk about per se.
- **Let's work on our communication around RWD/RWE. And lets be clear!**

Remember, say what you mean



Remember, say what you mean

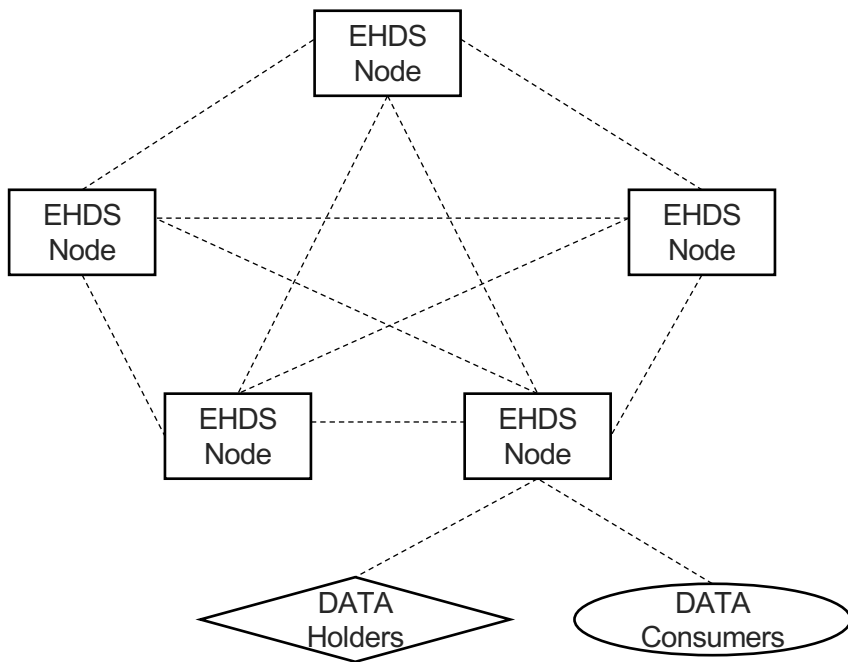


Communication isn't just between humans

- There is also Data communication
 - And here we go again...
 - What are we talking about and in which context
 - Who needs to be at the table to ensure that 'data' talks with one another?
- More is not necessarily better if the communication isn't working



EHDS concept



EHDS nodes = *Trust Anchors*

EHDS NODEs are resilient entry points for stakeholders into the EHDS

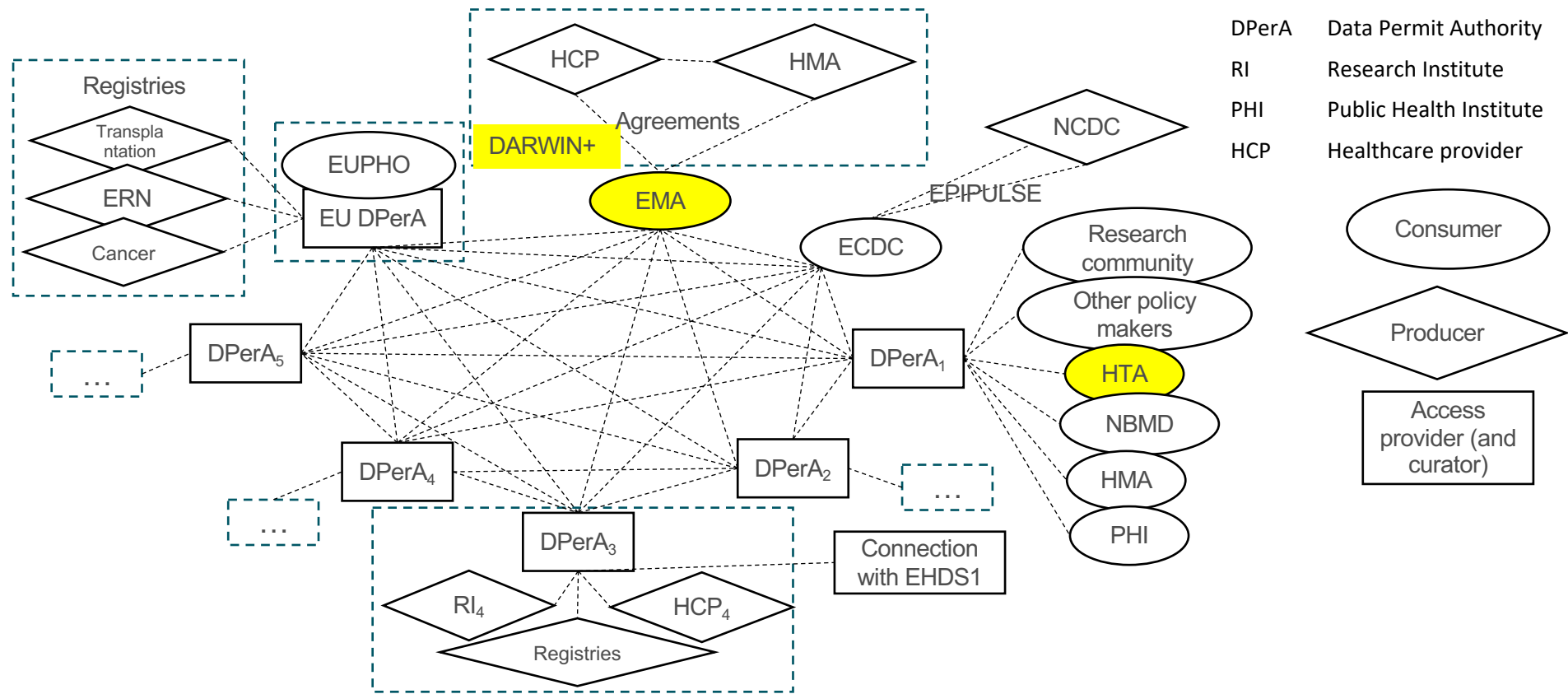
EHDS NODEs can be established by National or Trans-national stakeholders

EHDS NODEs follow common policies and interoperability specifications

DATA Holders make health data available for secondary use

DATA Consumers further process data for research, policy making or regulation

EHDS data infrastructure ecosystem



Where some might have gone wrong a bit

- Begin at the beginning and go on till you come to the end; then stop.

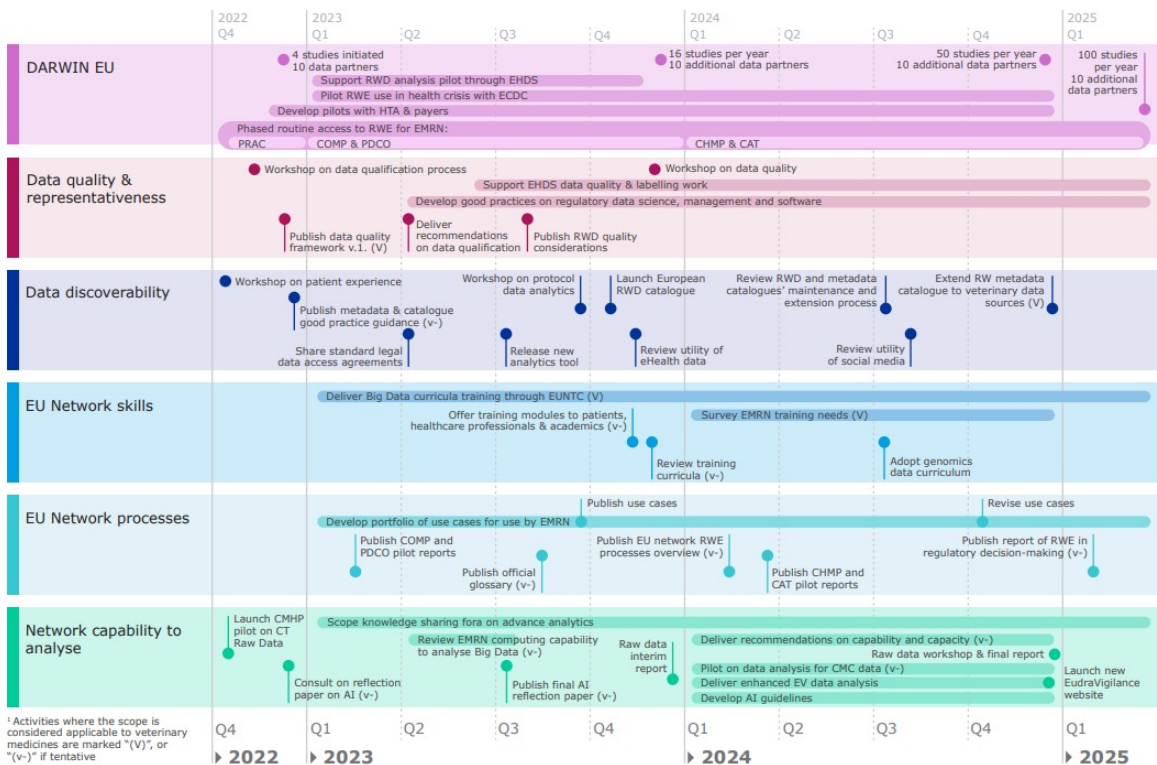
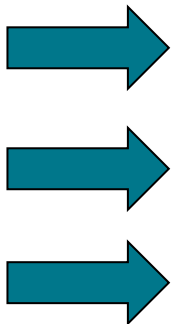


Where some might have gone wrong a bit

- Begin at the beginning and go on till you come to the end; then stop.
- Try to understand your data



HMA-EMA Joint Big Data Steering Group work plan



* Activities where the scope is considered applicable to veterinary medicines are marked "(V)", or "(v-)" if tentative





- Delivery of expert advice
- Governance framework
- International initiatives
- Stakeholder engagement
- Veterinary recommendations

Where some might have gone wrong a bit

- Begin at the beginning and go on till you come to the end; then stop.
- Try to understand your data
- Decide when and how you want to use it



What analyses and studies will DARWIN EU® deliver?

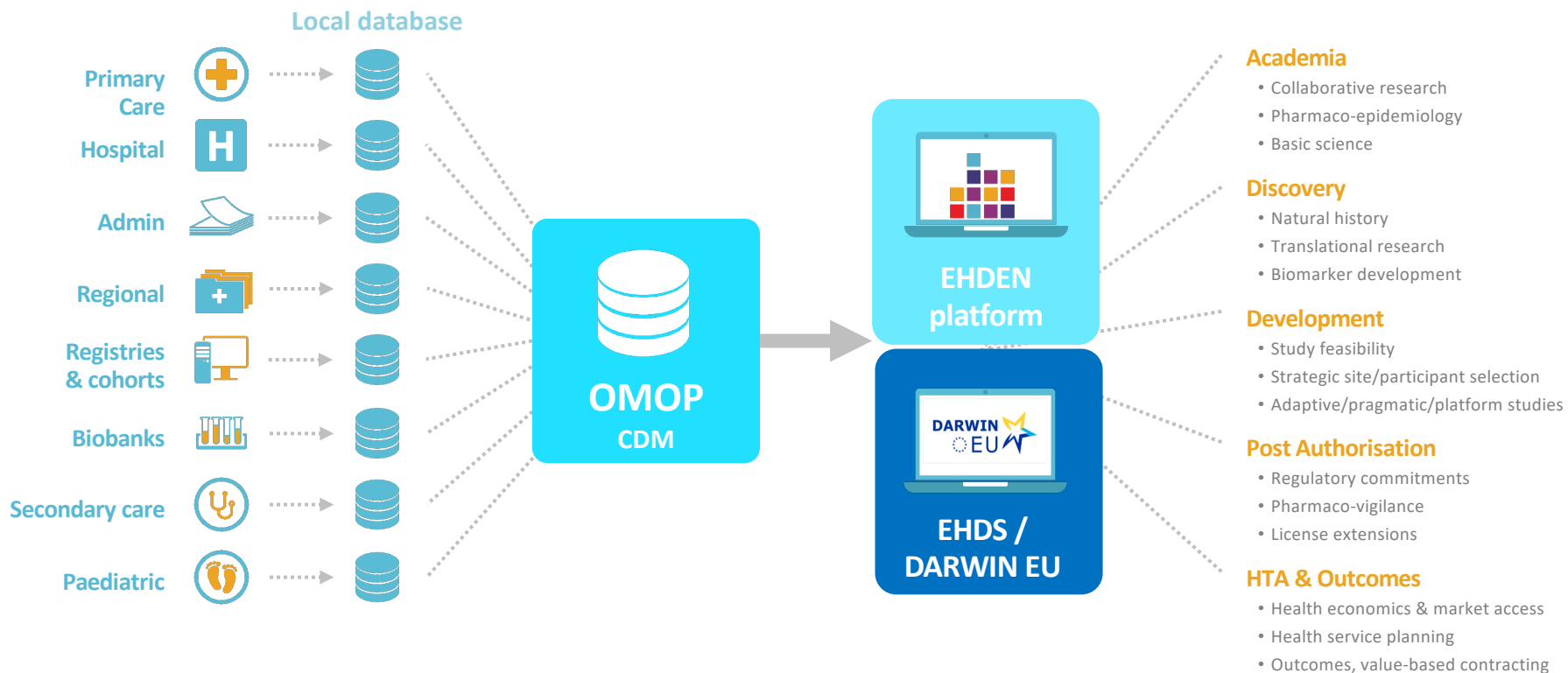
Category of observational analyses and studies	Description
 Off-the-shelf studies	<p>Studies for which a generic protocol is adapted to a research question</p> <ul style="list-style-type: none"> • Periodical estimation of drug utilisation • Safety monitoring of a medicinal product • Estimation of the incidence of a series of adverse events
 Complex Studies	<p>Studies requiring development or customisation of specific study designs, protocols, phenotypes, etc</p> <ul style="list-style-type: none"> • Estimate the prevalence, incidence or characteristics of exposures • Estimate the prevalence, incidence or characteristics of health outcomes • Describe population characteristics
 Routine repeated analyses	<p>Routine analyses based on Off-The-Shelf or Complex Studies (see above), repeated periodically with a pre-specified regularity (e.g. yearly)</p> <ul style="list-style-type: none"> • Etiological study measuring the strength and determinants of an association between an exposure and the occurrence of a health outcome considering sources of bias, potential confounding factors and effect modifiers
 Very Complex Studies	<p>Studies which cannot rely only on electronic health care databases, or which would require complex and/or novel methodological work</p> <ul style="list-style-type: none"> • Studies where it may be necessary to combine a diagnosis code with other data such as results of laboratory investigations, or studies requiring additional data collection

Where some might have gone wrong a bit

- Begin at the beginning and go on till you come to the end; then stop.
- Try to understand your data
- Decide when and how you want to use it
- Ensure your data sources talk to one another

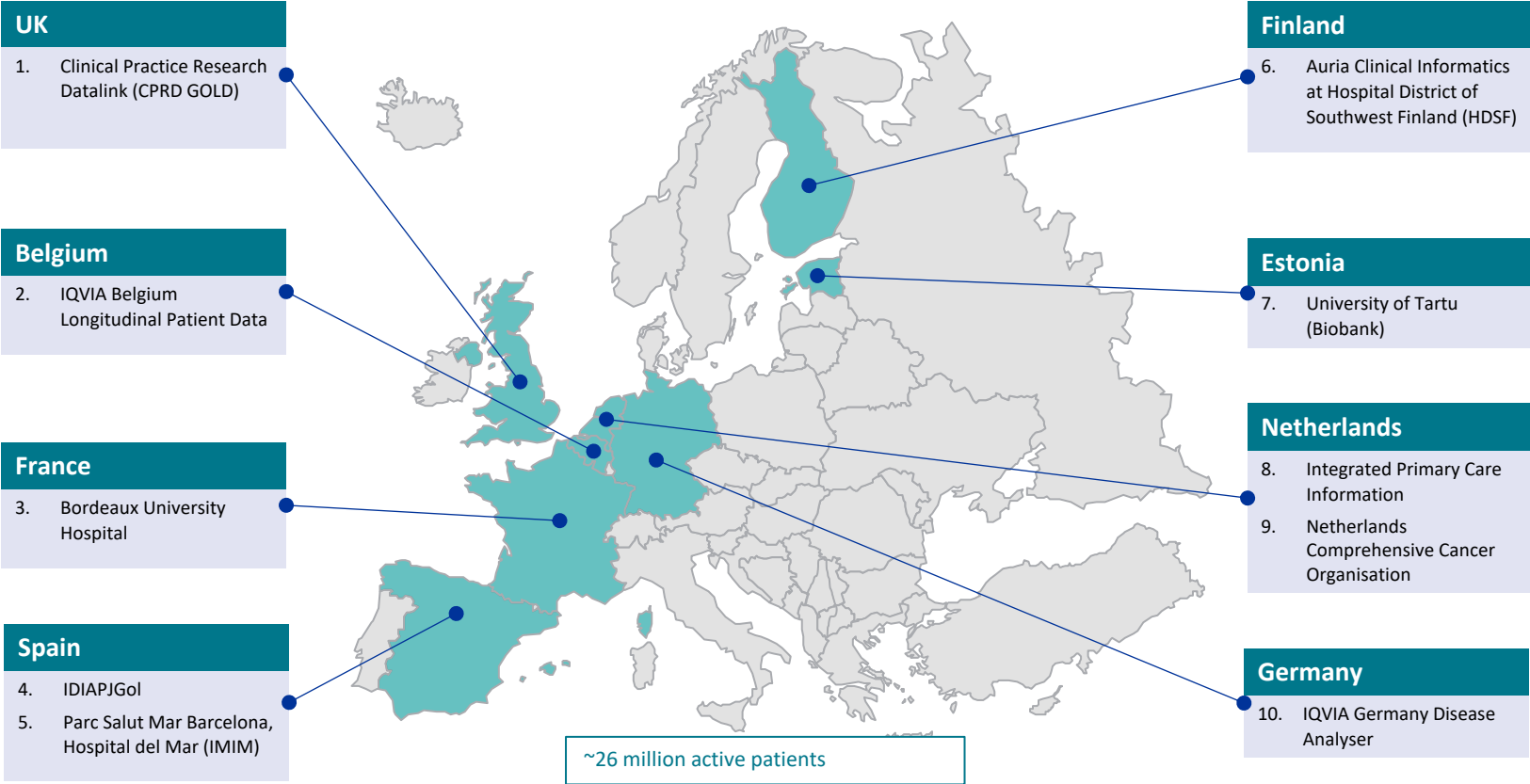


Language opens doors.....



Data partners – Year 1 (Phase I)

10 data partners in year one: additional 10 in year 2



Where some might have gone wrong a bit

- Begin at the beginning and go on till you come to the end; then stop.
- Try to understand your data
- Decide when and how you want to use it
- Ensure your data sources talk to one another
- Improve the data (big or small)
- Repeat!
- **Tomorrows RWD is generated today**



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