Data Standardisation Strategy - stakeholder workshop
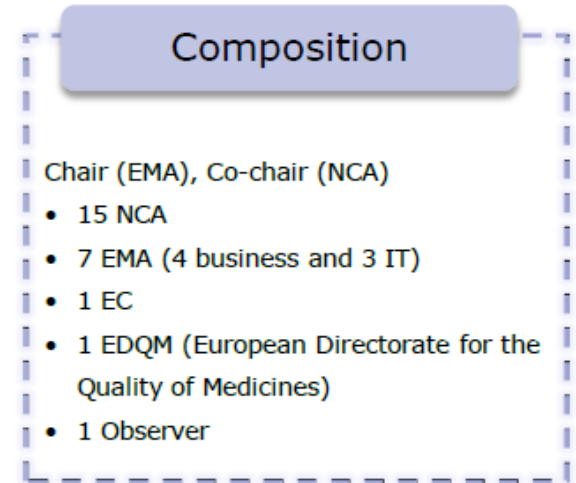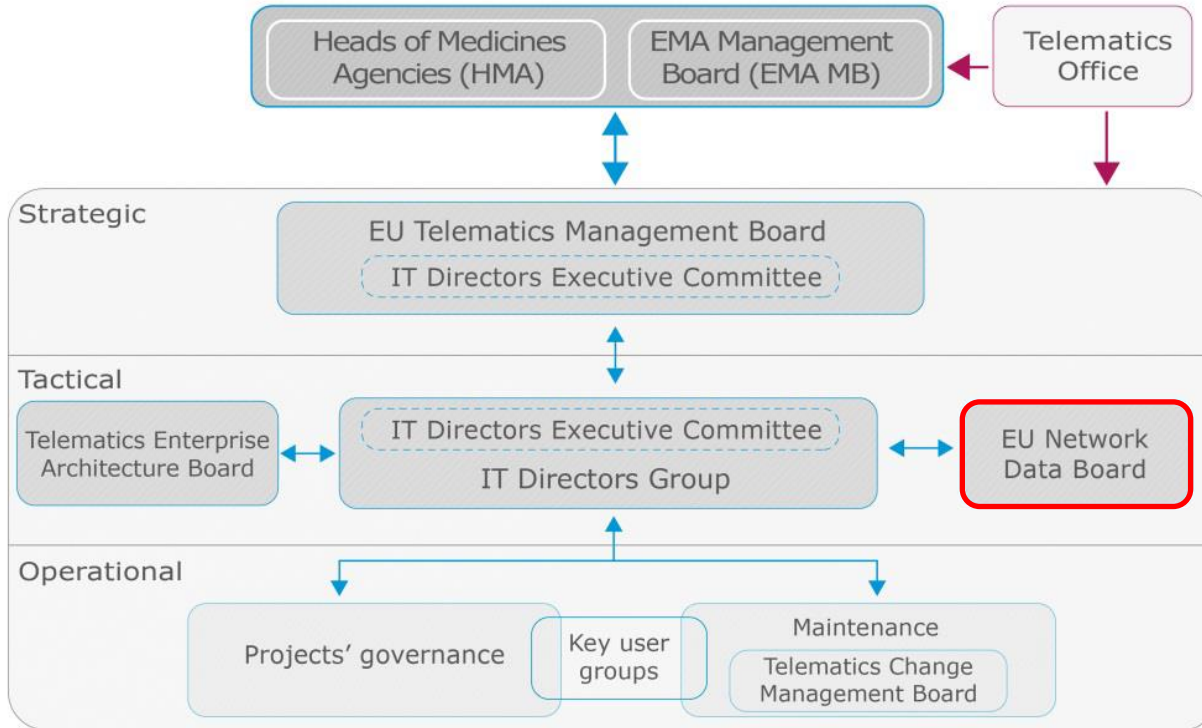
Session 2: Stakeholder's perspective and use cases

European Network Data Board

Peter Bachmann
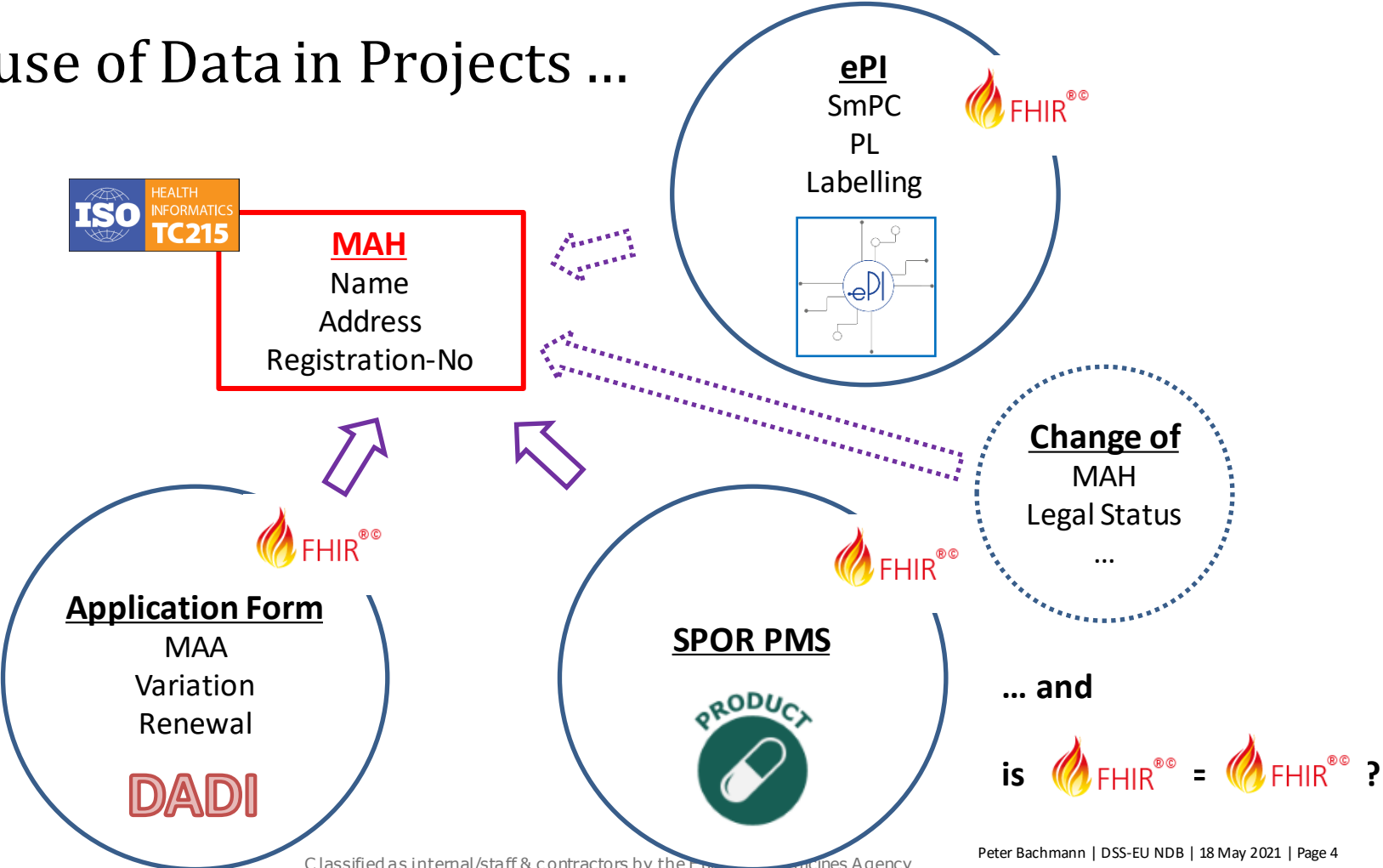
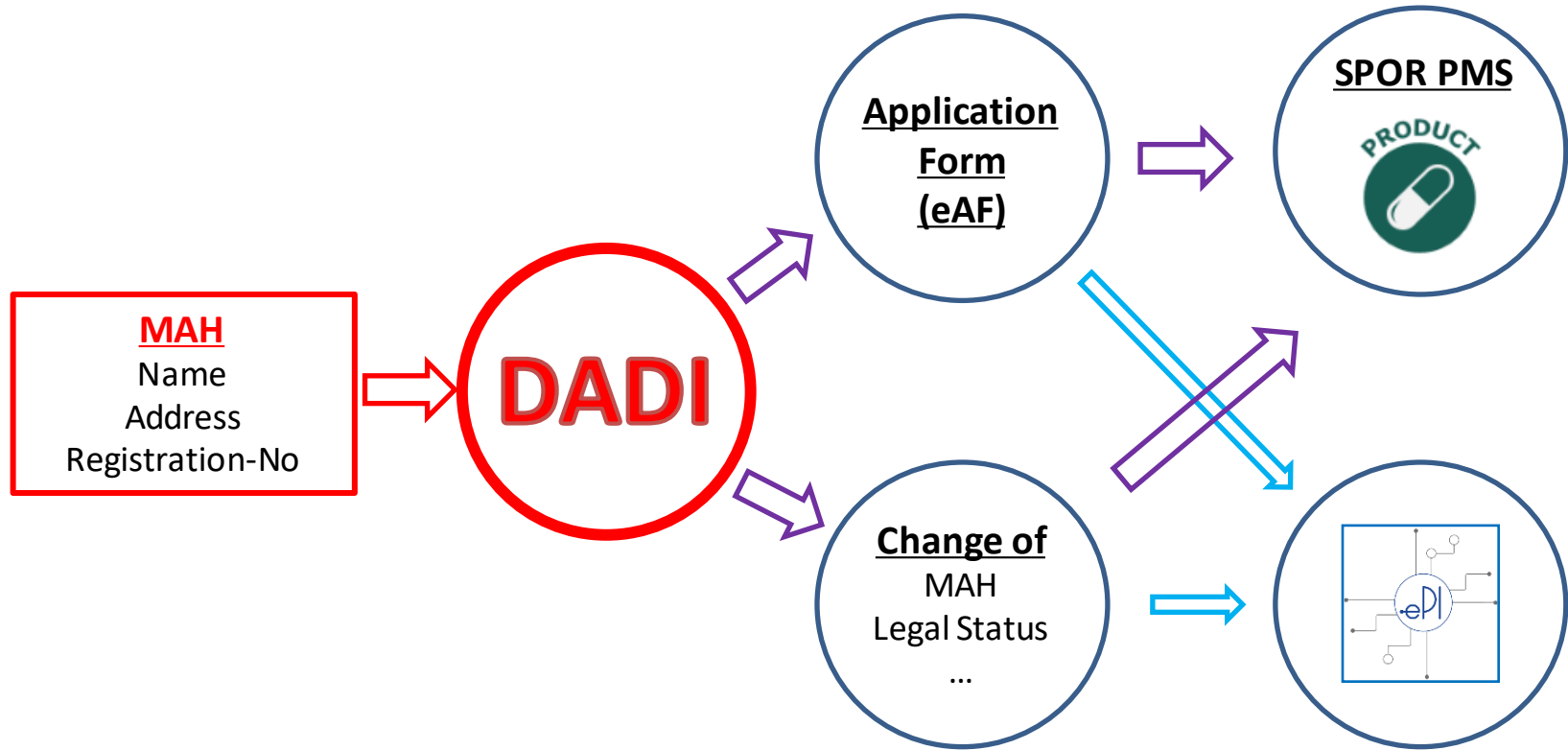# EU Network Data Board (EU NDB)

EU Network Data Board (EU NDB)

Role

- EU NDB is an advisory body which reflects the programme agreed by the EU Telematics Management Board (EU TMB) and Head of Medicines Agency (HMA) to manage the policies, principles and quality that will ensure access to accurate and risk-free data and information

- The Board is responsible for the development of the data management strategy, data related standards, including alignment with international standards, and the quality of master referential data (SPOR)

- Support and liase with IT DEC

From use of Data in Projects …

ePI
SmPC
PL
Labelling

🔥 FHIR®©

ISO HEALTH INFORMATICS **TC215**

MAH
Name
Address
Registration-No

Change of
MAH
Legal Status
…

🔥 FHIR®©

Application Form
MAA
Variation
Renewal

DADI

SPOR PMS

PRODUCT

🔥 FHIR®©

… **and**

is 🔥 FHIR®© = 🔥 FHIR®© **?**

… to the Flow of Data

MAH
Name
Address
Registration-No

DADI

Application Form (eAF)

SPOR PMS
PRODUCT

Change of
MAH
Legal Status
…

ePI

Visions

Short term

- Structured data we already have in the EU/EEA

  ➡️ let them flow!

Long term

- Structured data we don't have
- Structure/Data structure not in our hands

  ➡️ let's start the discussion now!

Manufacturing of a Medicinal Product

Current

• Information in eCTD Module 2 and 3 as free text

Goal:

• restructuring in
  • human readable (assessment)
  • structured (machine readable) data for the manufacturing of the
    • active substance/excipient
    • medicinal product

Conclusion

We need to move away from

IT-Projects

to

Network (Business) Projects

Let's utilise the power of structured data supporting our business processes

Thank you very much for your attention!

Contact

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