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Cross-border medical research: What are the new challenges arising from the forthcoming data protection legislation?

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Territorial scope & applicable legislation: general considerations

- Regulation -> little left for national law:
  - Supervisory Data Protection Authorities (DPA) in each country
  - Law of controller & law of processor(s) apply
  - Each organization communicates with DPA in its country
  - One stop shop in limited cases where cooperation is needed

Scientific research: too much room for national interpretation is a major threat (I)

- Rec 156: “Member States should provide for appropriate safeguards for the processing of personal data” e.g. conditions for pseudo-anonymization
- Art 9: Processing of special categories of personal data (Health data)
  - Paragraph 4: “Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health“

e.g. EORTC has valuable 50 years old repository of data and material; most patients are not alive anymore (so a priori out of the scope of GDPR); consents are not in line with GDPR and do not speak about sequencing (too old!!!)
What if some Member States prohibit further genetic research?
Valuable source of learning about disease (cancer) will be lost!!!

Scientific research: too much room for national interpretation is a major threat (II)

- Art 89: Member State law may provide derogations from some rights (such as the right to access by data subject) leading to heterogeneity: what if patients move within EU?

- Which law applies for the application of art 9(4) and 89?
  - Place of research? or place of residence of subjects?

What are we speaking about?

Chain of custody for biological material

Biobank Processor (LU)

Clinical trial consent
Further research? Yes!

Patient treatment as per CT & more)

Name = N°321

Central TR lab Processor(NL)

15 years later….
New research project
researcher, sponsor & controller (ES)

Trial Database

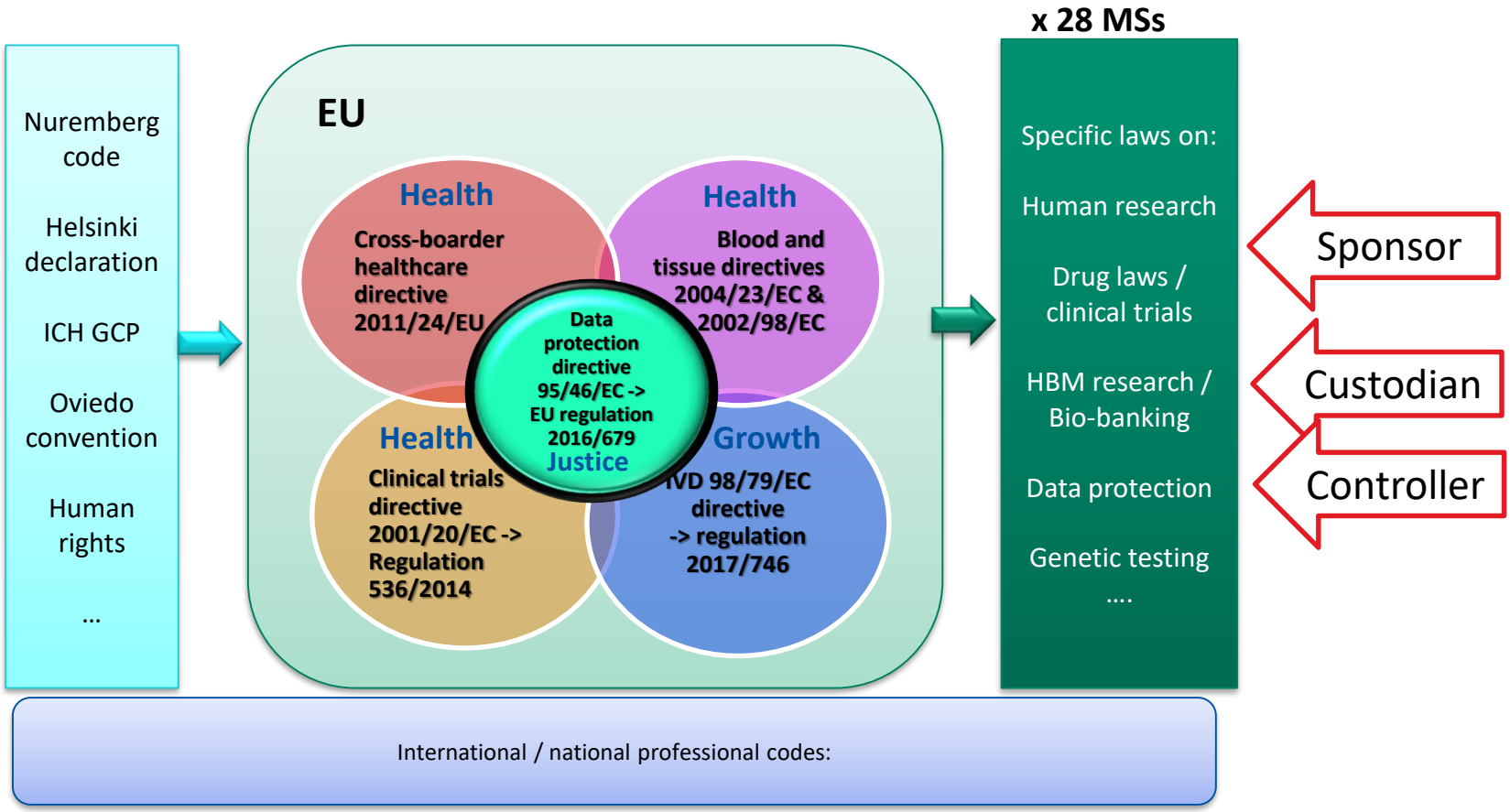
Sub-set of data
N°321
Data entered by the site
e-CRF on server in BE
or in the cloud

Hospitals (DK, DE, FR…)

Sponsor & controller (BE)

Sharing of data !!

More legislations apply to biomedical research…



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Diverging EU health regulations: The urgent need for co ordination and convergence

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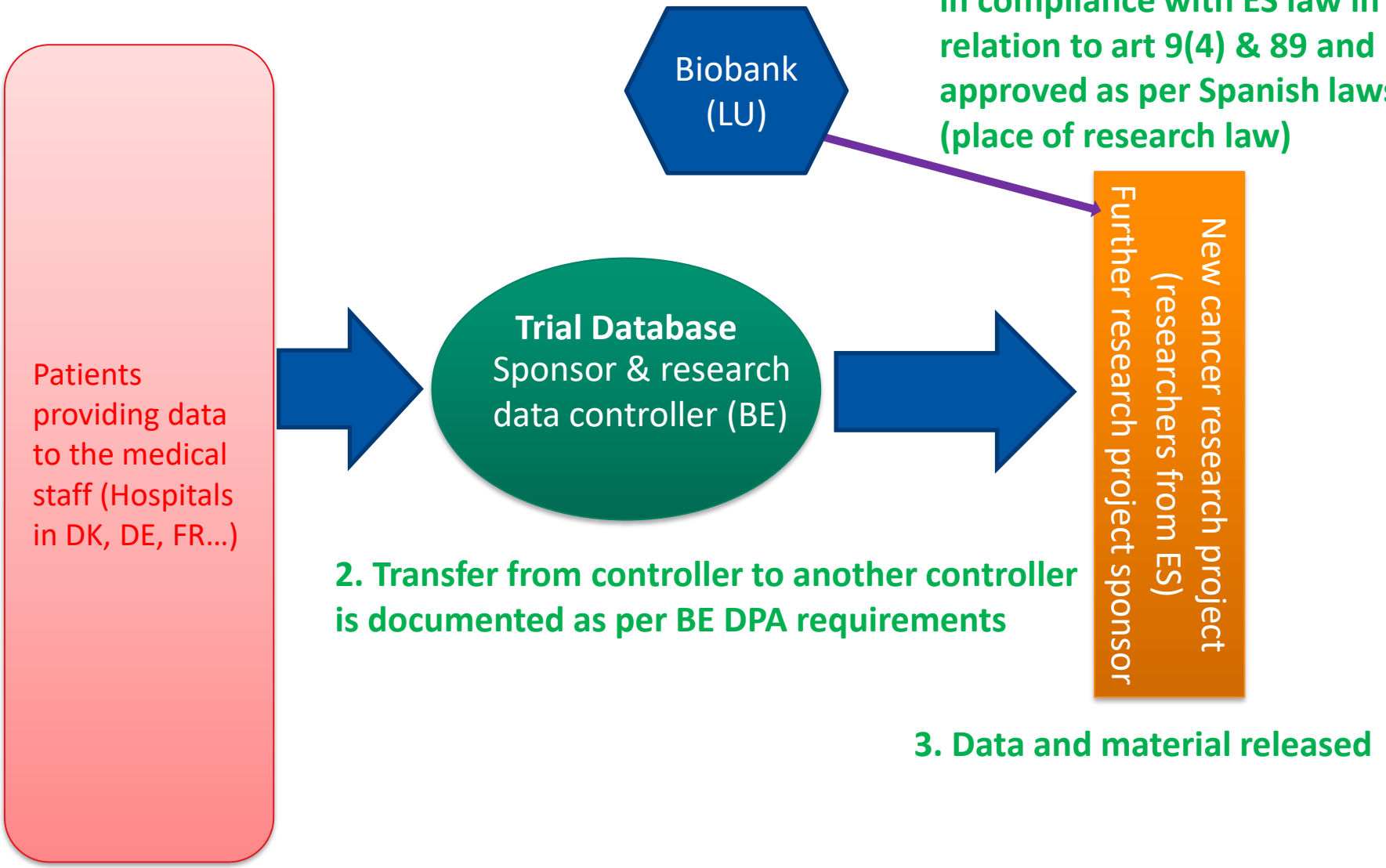
ABSTRACT

At the time of mayor breakthroughs in knowledge of molecular biology leading to change in design and conduct of innovative clinical research, there is a clear need for optimal co-operation at the EU level as well as with each Member States. The current legal framework for health research is developed and revised by several DGs dealing with clinical trials, data protection, in-vitro diagnostic tests and biomarkers. Also medical devices and advanced therapy directive / regulation have to be taken into consideration, all within a single trial/study. Such fragmentation of legal framework and national laws lead to several inconsistencies, wasting time and scarce re-

Constructive 3 steps proposal for Pan-EU further research



If Europe wishes to promote progress in Medicine and straighten EU competitiveness in the area of Health research, we must build streamlined legal framework

Unless the law of the place of research applies, biomedical research and medical progress will stop!!

Thank you