

WORKSHOP #3 Data Governance & Data exchange

Session 2

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Facilitators

Michel COLEMAN - London School of Hygiene & Tropical Medicine

Chuck WIGGINS - New Mexico Tumor Registry

Subtheme

- What legal steps/ agreements must be in place to enable data sharing/ access to data?

Discussants

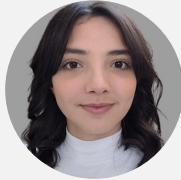


Philippe-Jean BOUSQUET

France

French National Cancer Institute

Director of Health survey, data-
science, and assessment division



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4.UNCAN.eu

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Senior Advocacy Officer

Workshop#3 Data governance and data exchange

Session 2: November 7, 2023

Discussants:

Dr Philippe Jean Bousquet – National cancer institute, France

Chloé Jego – UNCAN, France



French oncology data platform French national cancer institute

- Started in 2010
- Scope: Whole french population affected by a cancer, including cancer survivors
- Sources (not all available to date)
 - National insurance (claim database - available)
 - Cancer registries (first matches in process)
 - Data from screening program (not available)
 - Medical records – most important documents (newly authorized)
- Compliant with GDPR
- With a high level of security

Data sharing, what purpose?



Data warehouse - collect massive data over an extended period for re-use in multiple research projects.

ie. I keep and re-use the data how I want

→ The French data platform



Research project – meet a precise scientific objective with a limited timeframe

ie. I can only treat the data for the research purpose define in my protocol



After transfert, the owner of the data is the one who received the data

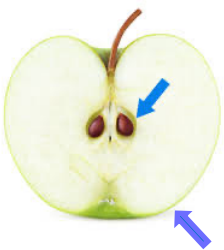
Which data?

Core dataset – For data warehouse

Knowing that these data can be very useful for other research subjects
But not sufficient for the research of the one who collects them

ie. The minimal dataset that should be (freely) shared

→ Data shared in the platform



Extra dataset – For dedicated research


The most sensitive data for the one who collects them

ie. The extra dataset that could be shared under restrictions


→ At first, remain in the provider platform but can be shared

What governance?

Scientific and ethic committee

- 
- For all researches
 - Independent members (*ie. not representative of someone or a data provider*)
 - Evaluating relevance, method and ethics
 - Without taking into account links or conflicts between different projects or teams

For the data provider

- 
- Informed about all researches using its data
 - May issue a reasoned advisory opinion within the time limits set for the scientific and ethics committee

Which infrastructure?

Platform data warehouse

- Centralized platform
- GDPR compliant
- Allow several research projects at the same time



Researcher's platform

- Extract from the platform
- Must have a similar safety environment



Federative platforms



A European Initiative to UNderstand CANcer

*A unique worldwide digital platform to share
and access high-quality research data*



AMBITION

September 1, 2022

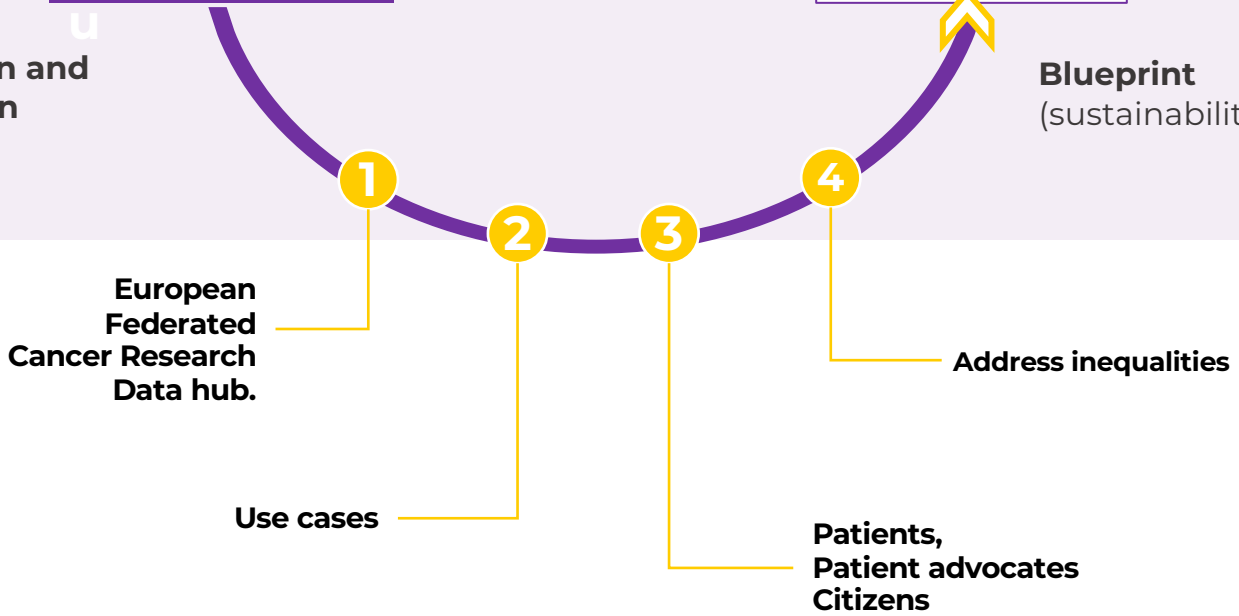
November 30, 2023

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A Coordination and Support Action

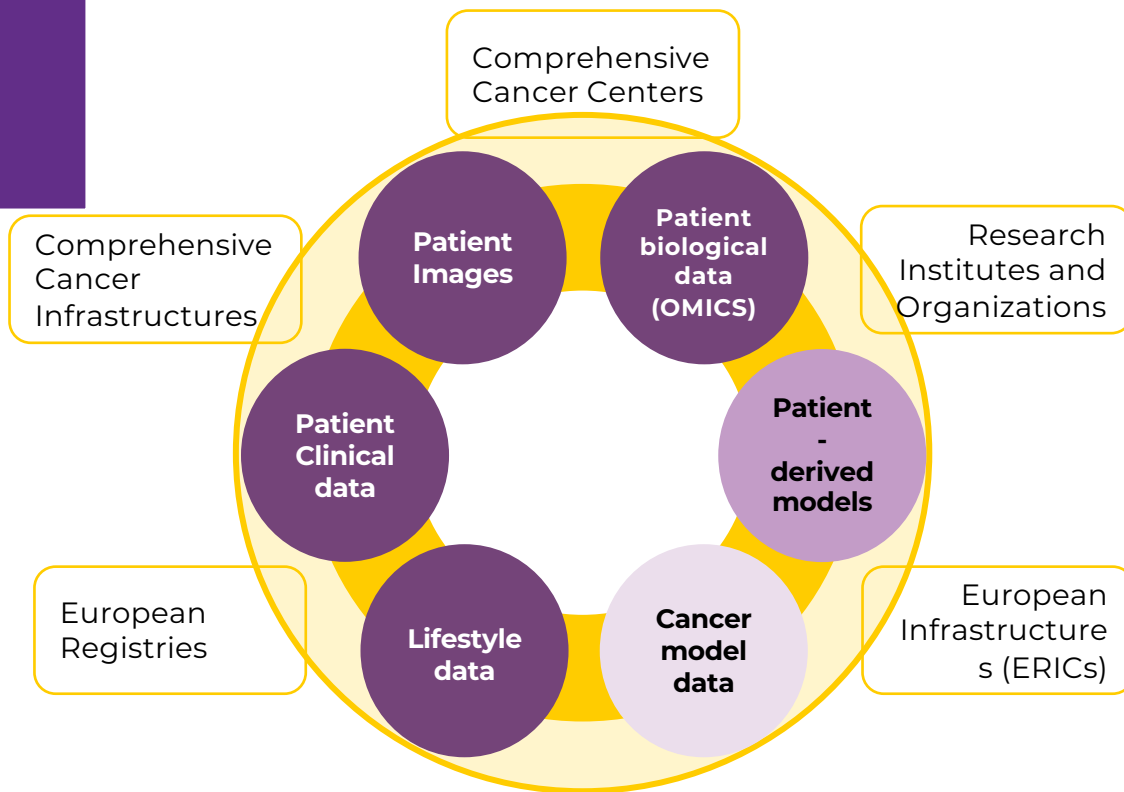
Blueprint
(sustainability, governance)



UNCAN.eu platform data collection

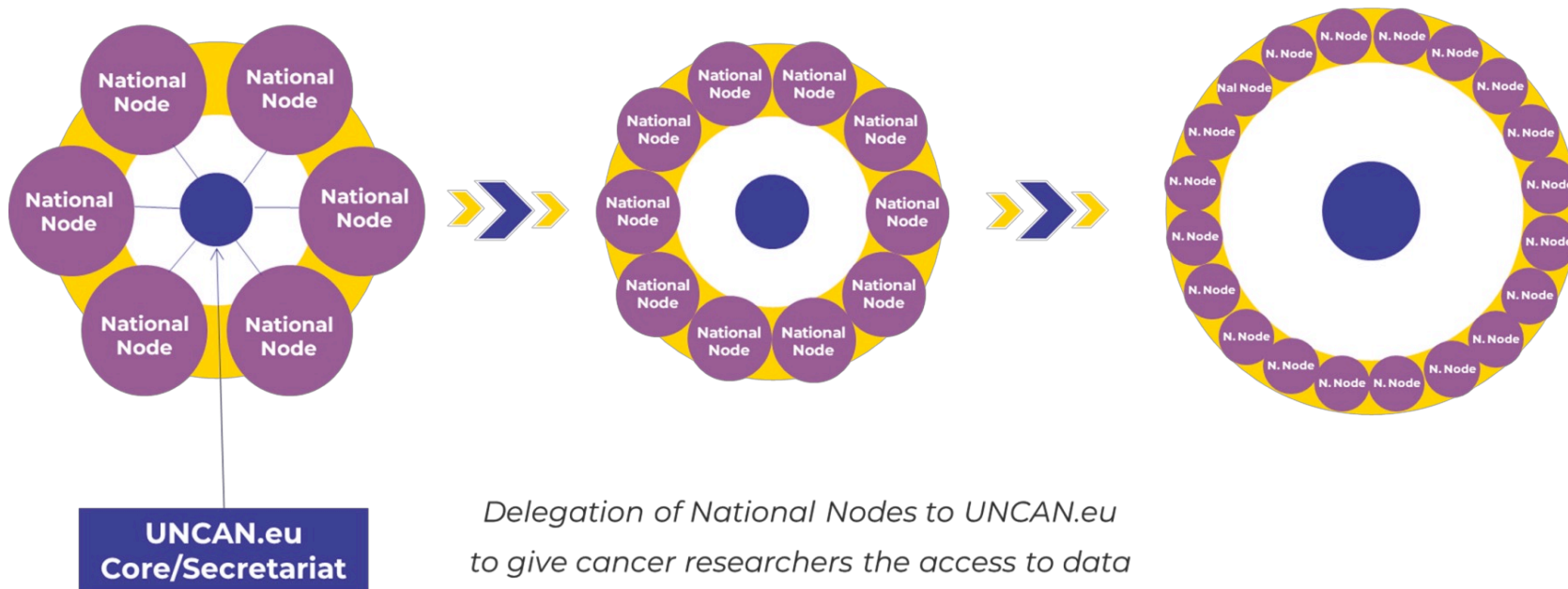
Data hub

A unique collection of
cancer research data
worldwide



UNCAN.eu network : a federation of federation

A stepwise implementation of the EU platform



UNCAN.eu : centralised data access process



Strategy Roadmap: 7-year vision

Start with EOOSC4Cancer

- clinical data, omics, images,
- focus on colorectal cancers

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- Extend to all cancer types
- Extend to models

Enrich with the support of

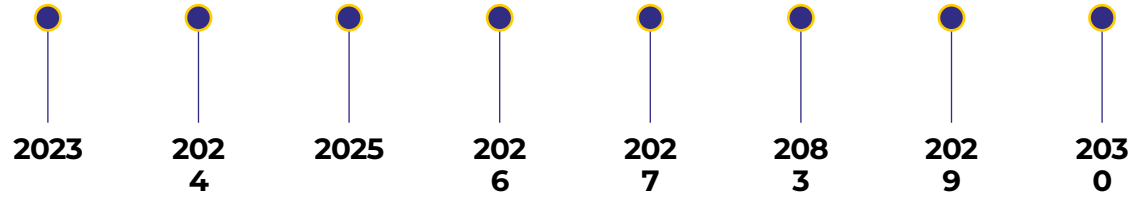
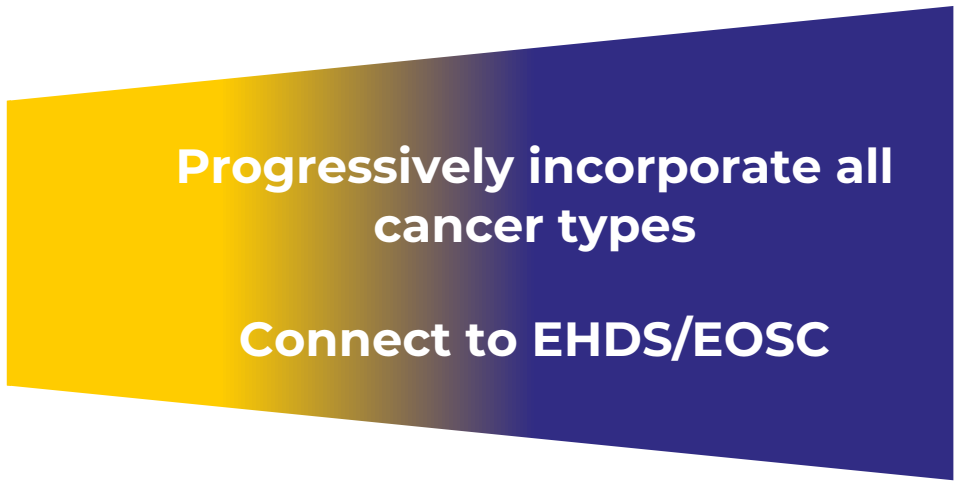
- EUCAIM, images
- CanSERV,
- ELIXIR, data management,

Align with

- European Health Data Space legal framework

Connect to:

- EHDS data access bodies
- European Open Science Cloud



European Initiative to UNderstand CANcer (UNCAN.eu)

Towards the creation of unique digital platform where researchers from all over the world share and have access to high-quality research data



This project has received funding from the European Union's Horizon Europe Coordination and Support Actions programme under grant agreement No 101069496

GOVERNANCE FRAMEWORK

DECISION-MAKING

General Assembly
*European Commission and
all the stakeholders*

**Stakeholder
Forum**

**Board of
Directors**

**Strategic Scientific
Board**

**Administrative
and Management
Unit**

**Director
General**

EXECUTIVE

Core secretariat

- Chief Technology Officer**
- Chief Operating Officer**
- Chief Coordination Officer**
- Chief Communication Officer**

DATA HUB
elixir

- Data Archives Unit**
- Data Curation Unit**
- Data Processing Unit**

**Legal,
Ethical
Unit**

**Data access
Unit**

**MS
Equality
Unit**

**MS Monitoring
Unit**

**Training
Unit**

**Communication
Dissemination
Unit**

-----> Advises —————> Appoints

OPERATIVE

Use cases : keystone of UNCAN.eu



Workshop: session 2
Data Governance & Data Exchange

*Paris Conference
for an International Childhood Cancer Partnership*

Rosa Castro, Incoming Director, Bioscience and Public Health Programme
European Academies Science Advisory Council (EASAC)

Nov 7 2023

European Commission GDPR first proposed text

2012–2015

2014–2015

EASAC–FEAM (and others) express concerns about ensuring proportionate mechanisms for protecting privacy while enabling health and scientific research to continue:
https://www.feam.eu/wp-content/uploads/Data_Protection_jointstatement_July2015-1.pdf

The GDPR started to apply

2018

Academies' early assessment of GDPR raises concerns about extra costs for research and delay/abandonment of projects:
https://www.feam.eu/wp-content/uploads/FEAM-Forum_Data-workshop-report_Final.pdf

2019

Schrems II judgment by the European Court of Justice invalidating the US Privacy Shield

2020

Start of ALLEA–EASAC–FEAM project

EDPB data-transfer guidance

2021

Publication of the joint ALLEA–EASAC–FEAM report on International Sharing of Personal Health Data for Research



International Sharing of Personal Health Data for Research

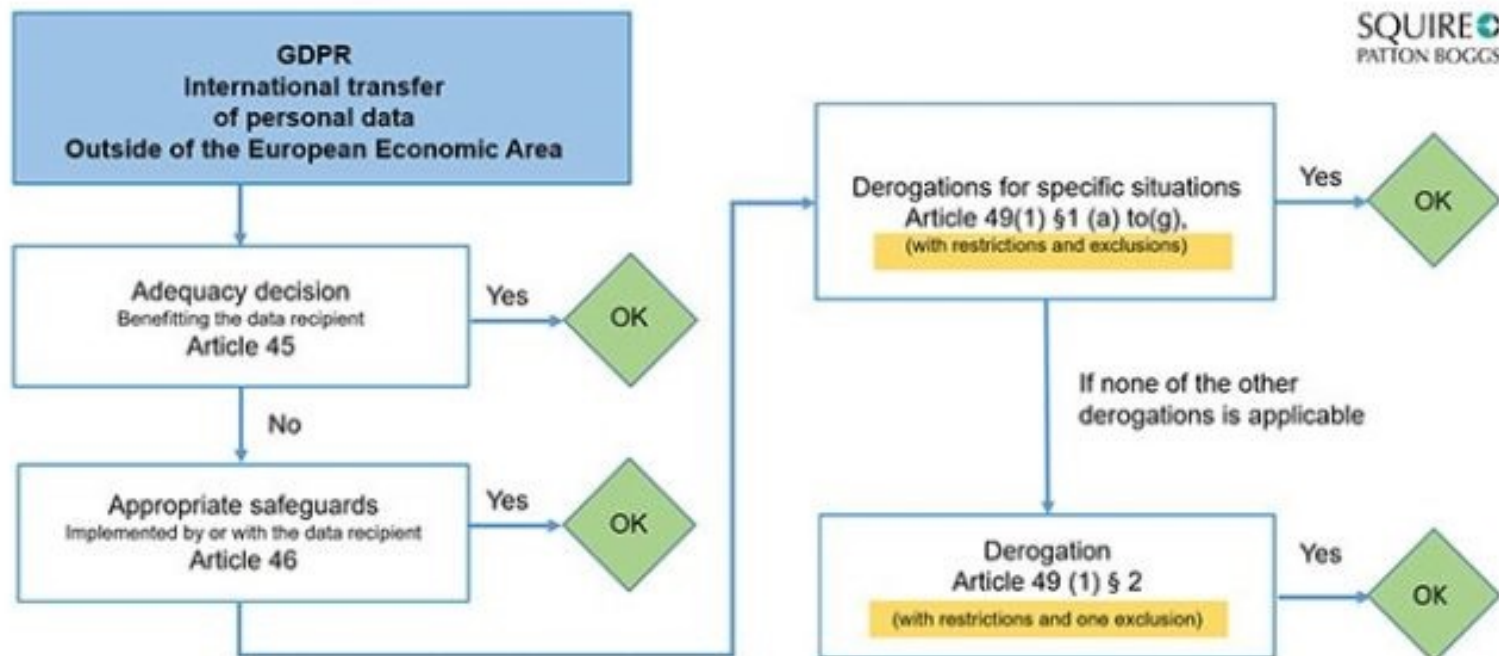
April 2021



Joint report by [ALLEA](#), [EASAC](#), [FEAM](#)

GDPR & optimal data sharing for research (International transfers)

- GDPR applies to pseudonymized data (but threshold for anonymity very high)
- International transfers (outside of EEA/EU +EU Member States plus Iceland, Liechtenstein and Norway) need to be adequately protected
 - Adequacy decision
 - Appropriate safeguards
 - Derogations
- Issues with public sector institutions in many countries (e.g., USA)
- UK after Brexit: adequacy decision (sunset clause, 2025...)



After having first endeavored possibilities to frame the transfer with one of the above (EDPB Guidelines 2/2018)

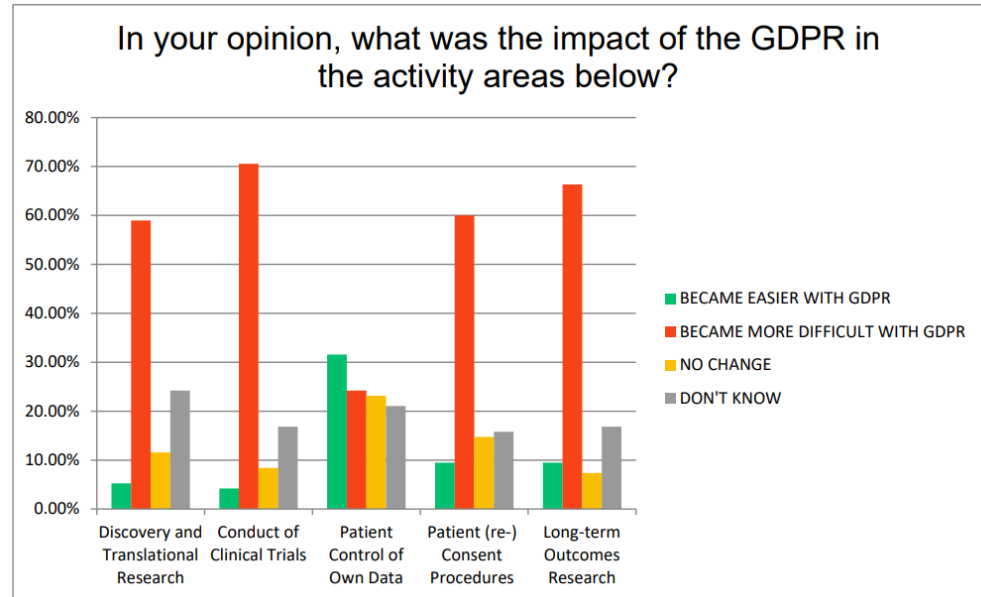
GDPR & optimal data sharing for research

- Solutions: (1) better options within article 46 of the GDPR; (2) guidance by the European Data Protection Board; (3) examples & guidance for health researchers
- Interoperability, and other methodological and technical quality issues should also be addressed to facilitate efficient and secure data sharing for research
- Privacy enhancing technologies can improve data security, but do not circumvent GDPR data transfer requirements

What has happened since the joint report was published?

- The EU-US has now agreed a process for private sector sharing to replace Privacy Shield, however, this is likely to be challenged again in the ECJ
- The public sector problems persist
- The joint report identified cancer research and care as a major concern for data sharing
- The journal Lancet Oncology: GDPR obstructs cancer research data sharing - The Lancet Oncology
- Survey of cancer experts finding impediments by the GDPR: The impact of the EU General Data Protection Regulation on childhood cancer research in Europe - The Lancet Oncology

GDPR & optimal data sharing for research



Source: [Vassal, G., Lazarov, D., Rizzari, C., Szczepański, T., Ladenstein, R., & Kearns, P. R. \(2022\). The impact of the EU General Data Protection Regulation on childhood cancer research in Europe. *The Lancet Oncology*, 23\(8\), 974-975](#)

What international research collaborations are at risk?

- About 5,000 collaborative projects between the US National Institutes of Health (NIH) and EEA countries
- At least 40 clinical and observational studies on risk factors and exposures for cancer suspended or delayed
- Research projects within the National Cancer Institute Cohort Consortium (cohort studies worldwide) suspended or delayed
- Statens Serum Institut in Denmark halted transfers of personal data to the NIH within a collaboration on diabetes
- The World Health Organization's International Agency for Research on Cancer (IARC) also affected

Institutions involved

- EU Commission: Directorates-General justice, health and research
- European Parliament
- European Council –member states
- Cooperation with other countries

Institutions involved: EDPB

- Created to ensure a consistent application and enforcement of data protection law across the European Economic Area, EEA
- The EDPB:
 - adopts binding decisions to settle disputes when national Supervisory Authorities (SAs) enforce the GDPR and do not reach an agreement on a cross-border case
 - provides general guidance to clarify and promote a common understanding of EU data protection laws
 - adopts opinions addressed to the European Commission or to the national Supervisory Authorities
 - promotes and supports the cooperation among SAs