CELGENE PAGE PROGRAM

PRIVACY ACCOUNTABILITY GOVERNANCE ENHANCEMENT

GDPR: Mapping stakeholders

PCMG- GDPR one year on
Copenhagen, April 2, 2019

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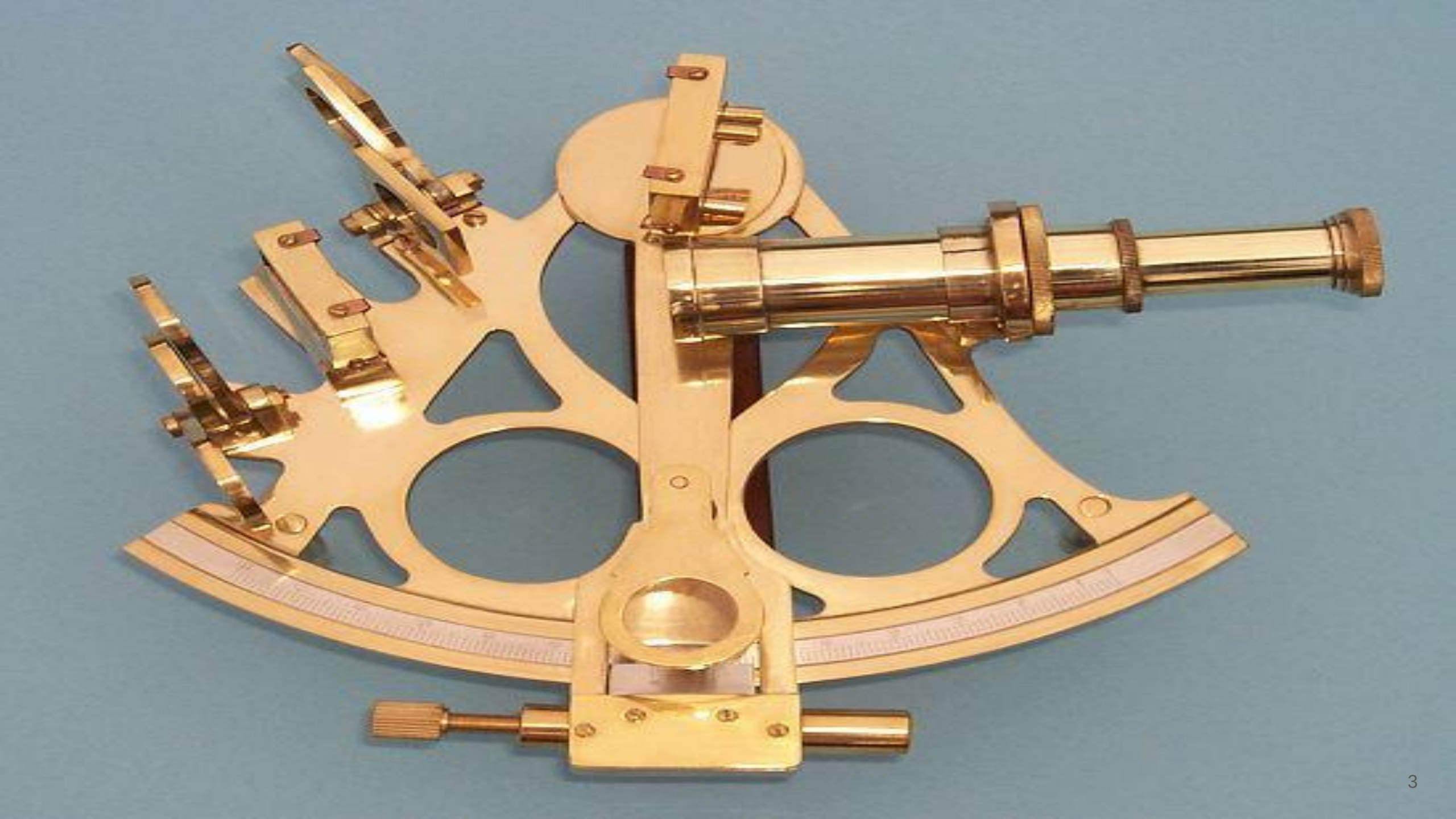
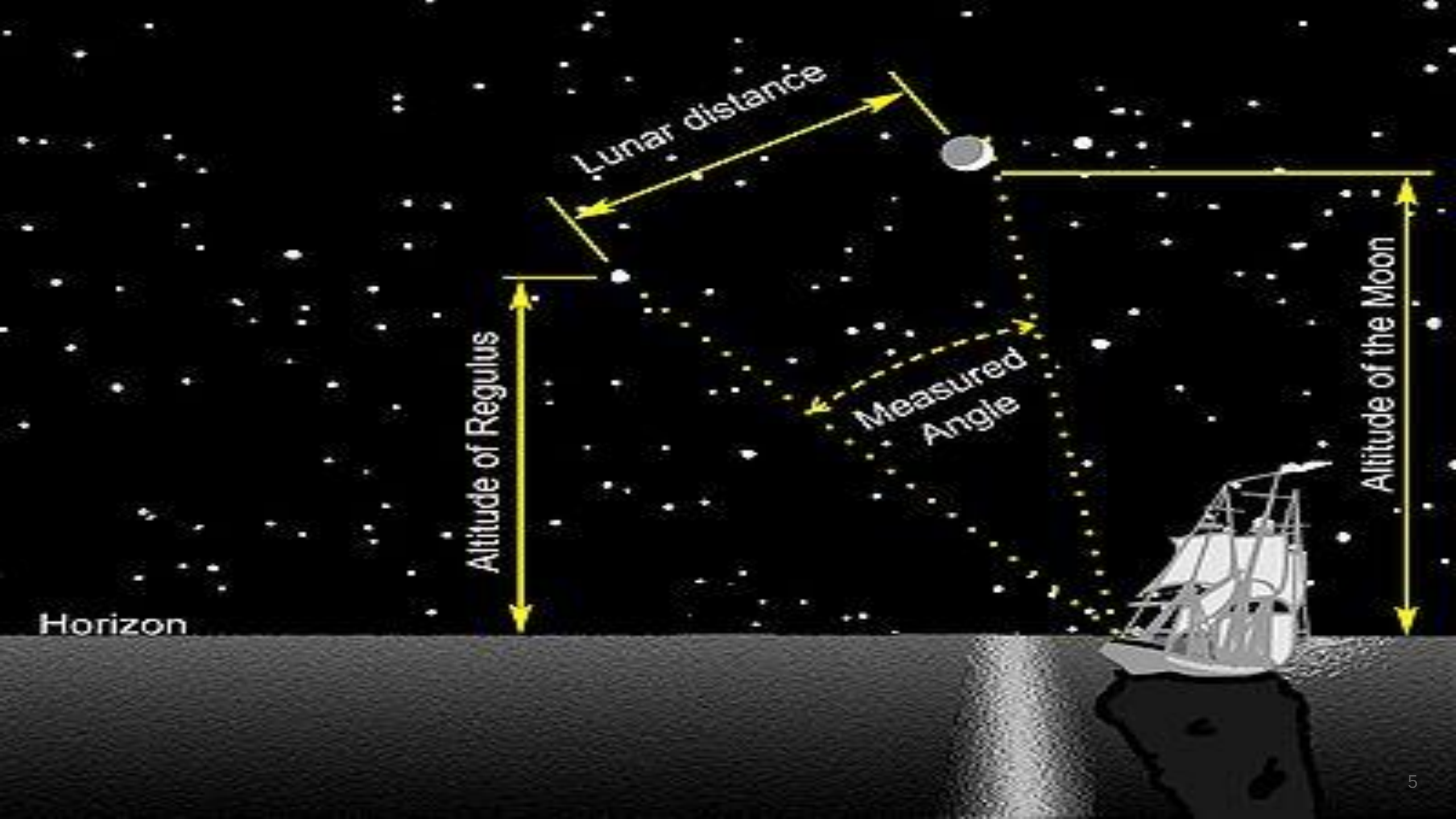
Chief Privacy Counsel

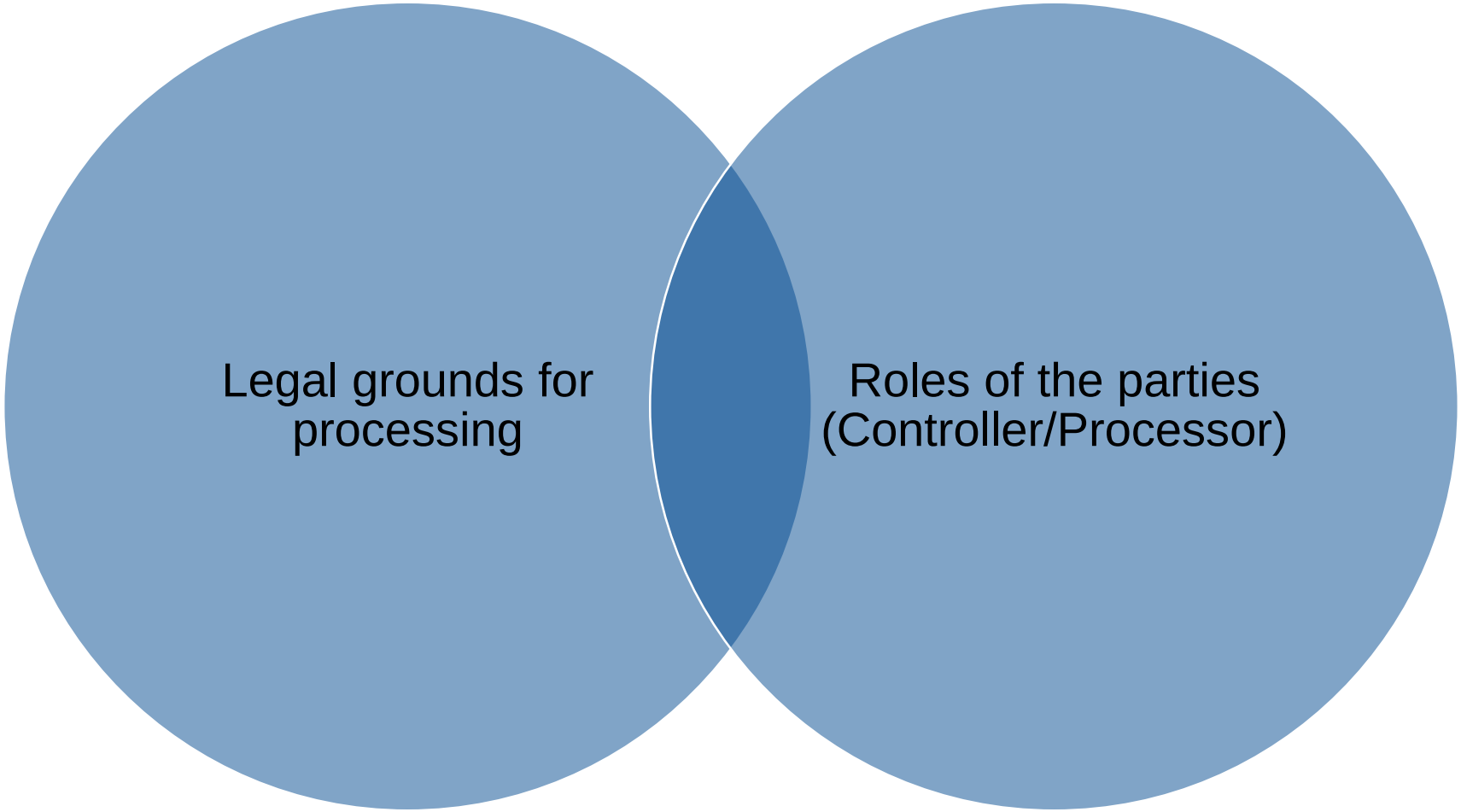
Disclaimer

- The views expressed in this presentation are the presenter´s and do not necessarily represent the views of Celgene




Lunar distance
Altitude of Regulus
Measured Angle
Altitude of the Moon
Horizon

Key GDPR concepts for scientific research



Legal basis- consent and other alternatives

Art. 6 (alternatives)	Art. 9 (alternatives)
• **Compliance with a legal obligation** (Art. 6(1)c)), understanding that the legal obligation is the clinical trial regulations (currently, national laws and the CTR in the near future). • **Legitimate interests in conducting scientific research** (art. 6(1) f)), which can be used by the private sector but not by public sites and public sponsors. • **Performance of a task in the public interest or in the exercise of official authority** (article 6(1)(e)), which can be used by public sites. • **Necessary for the performance of a contract** (art. 6(1)b), being this contract the acceptance by the patient to participate in the CT, as signified in the ICF.	• **Public interest in public health (**article 9(2)(i). • **Scientific research according to local/EU law, with safeguards** (Art. (9)(2)(j)), understanding that the law could refer to clinical trial regulations or any other that regulate biomedical research or scientific research studies.
• **Consent** (Art. 6(1)a).	• **Consent** (Art. 9(2)a)).
(in relying on consent, it must be taken into account that the withdrawal of a data protection consent in this context cannot entail the deletion of the data in order to comply with the GCP, safety laws and art. 17(3)d) GDPR)	

Data Controller vs Data Processors (clinical trials)

Sponsor

Clinical trial sites

Joint controllers

Data processor

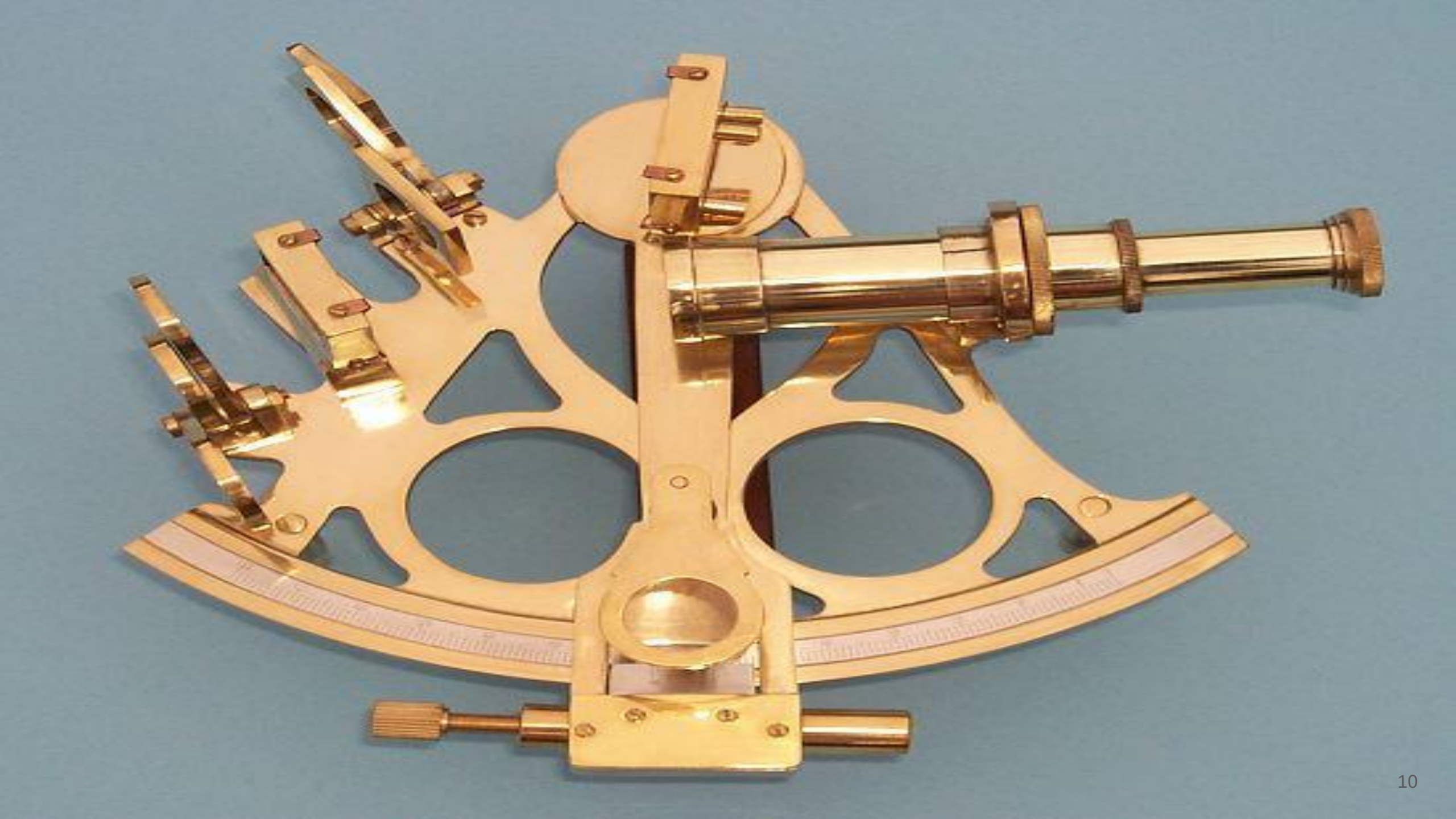
Separate controllers (“Co-Controllers)

Co-Controllers and Data Processor for coded data

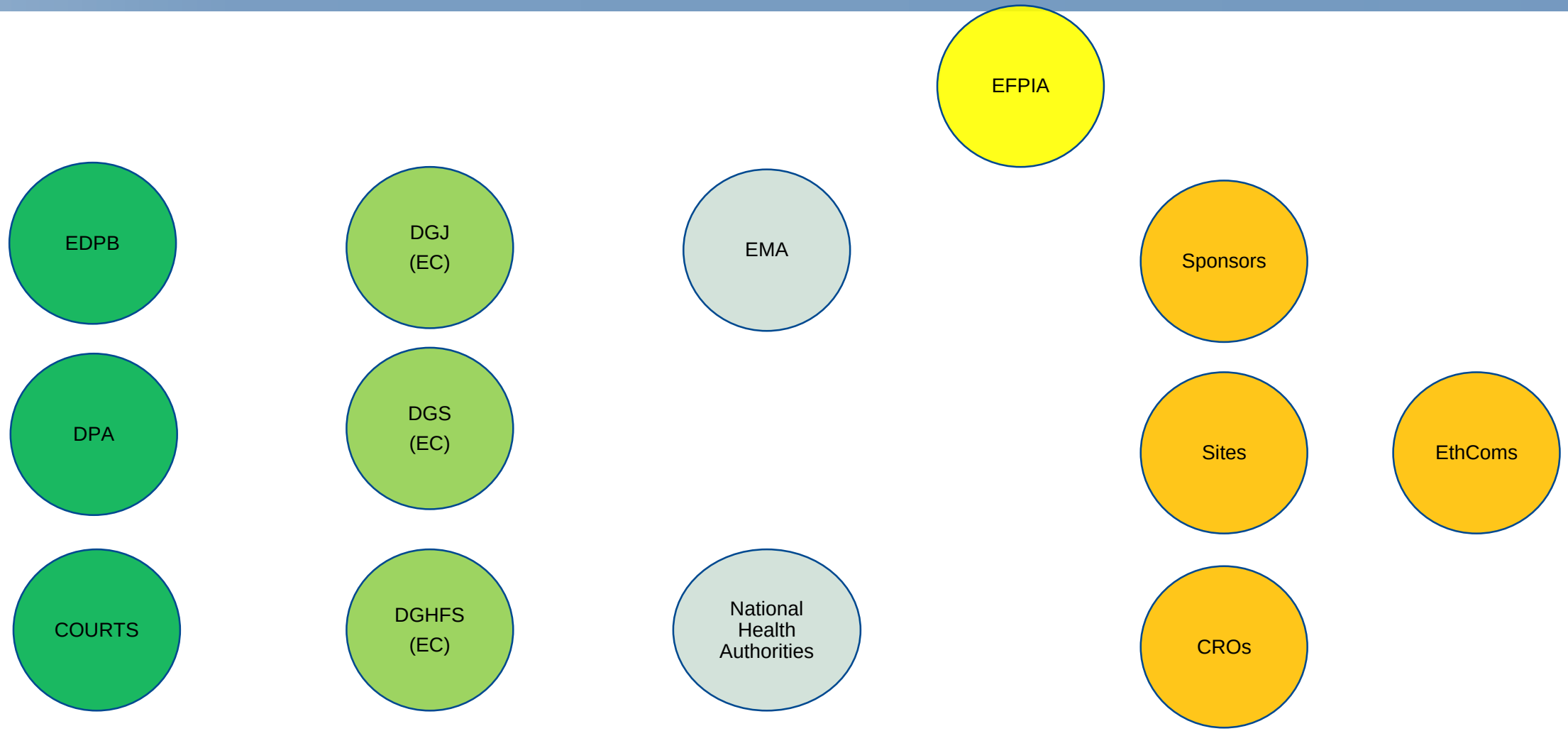
CROs

Other Vendors

Data processor



Stakeholders' map –flawless celestial navigation?



UK (NHS): No consent – Art 6

NHS
Health Research Authority

Historically, most research studies that have involved use of confidential patient information have sought consent from participants. This meets ethical expectations to promote the autonomy and privacy of research participants. Legally speaking, consent was obtained to avoid a breach of the common law duty of confidentiality. This is not changing with the introduction of the GDPR.

The GDPR requires each activity of processing data to have a legal basis under this legislation, in addition to the common law basis. For health and social care research, the legal basis is determined by the type of organisation:

- for universities, NHS organisations or Research Council institutes the processing of personal data for research will be a 'task in the public interest'
- for commercial companies and charitable research organisations the processing of personal data for research will be undertaken within 'legitimate interests'.

For the purposes of the GDPR, the legal basis for processing data for health and social care research is **not** "consent". This means that requirements in the GDPR relating to consent do **not** apply to health and care research.

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/consent-research/

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UK (NHS): separate controllers + site is processor for research study

NHS
Health Research Authority

It is the sponsor who determines what data is collected for the research study through the protocol, case report form and/or structured data fields in a database. The sponsor therefore acts as the controller in relation to the research data.

In many cases, participants will be patients/service users and the same information may also be provided to the care organisation. The care organisation therefore acts as the controller in relation to the data provided for care purposes. This means that there may be two controllers for the same information – but for two different purposes.

This distinction between the purpose for which data is collected is important in determining whether the sponsor is collecting personal data directly from the data subjects (ie participants) or indirectly. If the purpose of the collection at the time it was obtained was only to support the delivery of care and the individual was not participating in the study, then the controller is the care organisation. If that personal data is then transferred to a separate research sponsor, the sponsor has obtained the data indirectly, and becomes the controller for the processing of that data for research purposes.

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/data-controllers-and-personal-data-health-and-care-research-context/

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France (DPA): no consent (arts. 6.1.f.+9.2.j)

CNIL.

Fondement légal du traitement des données lors d'une recherche dans le domaine de la santé

L'article 6 du RGPD liste les bases juridiques permettant de considérer que le traitement des données est licite. Le responsable de traitement doit s'appuyer sur l'un de ces fondements pour réaliser sa recherche. L'on pourra notamment s'appuyer sur :

- **la mission d'intérêt public** (article 6-1-e), par exemple : pour un organisme public, un CHU etc.,
- **l'intérêt légitime** (article 6-1-f), par exemple pour les industriels ou autres acteurs privés.

En outre, dans le cadre des recherches, le traitement des données de santé est possible au regard de **l'article 9.2 (j)** du RGPD, qui mentionne la nécessité de traiter les données à des fins de recherche scientifique.

En tout état de cause, s'agissant des MR-001 & MR-003, la notion de consentement évoquée dans le titre des MR-001 & MR-003 **fait référence au consentement exigé ou non par le code de la santé publique en fonction des catégories de recherche** (et de la loi « informatique et libertés » s'agissant de la réalisation d'un examen des caractéristiques génétiques) et ne renvoie pas au consentement au traitement des données à caractère personnel prévu à l'article 6-1-a ou à l'article 9-2-a du RGPD.

https://www.cnil.fr/fr/recherches-dans-le-domaine-de-la-sante-ce-qui-change-avec-les-nouvelles-methodologies-de-reference

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Czech Rep. (DPA): no consent (art. 9.2.h)

The processing of specific categories of personal data is carried out as part of a clinical trial of pharmaceutical products for human use because it is a type of processing that is necessary for reasons of public interest in the field of public health, such as protection against serious borderland health threats or the securing of strict quality standards and safety of healthcare, pharmaceutical products or medical devices, based on EU or a Member State's law providing appropriate and specific measures to secure the rights and liberties of the data subject, in particular, professional secrecy. ***In this case, it is processing under the provisions of Art. 9 (2) h) of the General Data Protection Regulation. Because of the existence of this legal title for processing sensitive data / special categories of personal data, consent of the subject with the processing of personal data is not necessary. In general, the data subject should not get the impression that his or her personal data is processed based on the consent, if this is not the case, as otherwise the subject is not being truthfully informed about his or her rights****."*

https://www.uoou.cz/stanovisko-c-3-2014-k-nadbytecnemu-vyzadovani-souhlasu-se-zpracovanim-osobnich-udaju-a-souvisejicimu-nespravnemu-plneni-informacni-povinnosti/d-11913.

Germany: GDPR allows for “no consent”

“Art. 27.1: By derogation from Article 9 (1) of Regulation (EU) 2016/679, the processing of special categories of personal data as referred to in Article 9 (1) of Regulation (EU) 2016/679 shall be permitted also without consent for scientific or historical research purposes or statistical purposes, if such processing is necessary for these purposes and the interests of the controller in processing substantially outweigh those of the data subject in not processing the data. The controller shall take appropriate and specific measures to safeguard the interests of the data subject in accordance with Section 22 (2), second sentence.

GDPR (as implemented): no consent if art. 9.2.j) + legitimate interests

Germany – medicines law: consent uber alles?

SIXTH CHAPTER
PROTECTION OF HUMAN SUBJECTS IN CLINICAL TRIALS

table of contents

Section 40
General conditions for clinical trials

(1) The sponsor, the investigator and all of the other persons involved in the clinical trial shall, in the conduct of the clinical trial of a medicinal product on human beings, fulfil the requirements of good clinical practice laid down in Article 1 paragraph 3 of Directive 2001/20/EG. The clinical trial of a medicinal product on human beings may only be commenced by the sponsor if the competent ethics committee has issued a favourable opinion on it pursuant to Section 42 sub-section 1 and the competent higher federal authority has given its approval pursuant to Section 42 sub-section 2. The clinical trial of a medicinal product may only be conducted on human beings if and as long as:

1. a sponsor or a representative of the sponsor whose registered place of business is situated in a Member State of the European Union or in another State Party to the Agreement on the European Economic Area, is available,

2. the foreseeable risks and inconveniences are medically justifiable, compared with the benefit for the person on whom the clinical trial is to be conducted (person concerned), and the anticipated significance of the medicinal product for medical science,

2a. according to the state of scientific knowledge in relation to the purpose of the clinical trial of a medicinal product consisting of a genetically modified organism or a combination of genetically modified organisms or containing such organisms, unjustifiable harmful effects on:

a) the health of third persons and

b) the environment

are not to be expected,

3. the person concerned:

a) is of age and is capable of understanding the nature, significance and implications of the clinical trial and to form a rational intention in the light of the facts,

b) has been informed pursuant to sub-section 2 sentence 1 and has given written consent, in so far as no deviating provisions are specified in sub-section 4 or Section 41, and

c) has been informed pursuant to sub-section 2a sentences 1 and 2 and has given written consent; consent must refer specifically to the collection and processing of health-related data,

GDPR consent?

Italy… sort of

GARANTE
PER LA PROTEZIONE
DEI DATI PERSONALI

DPA: No consent but safeguards to be determined by the DPA….

- (**some) sites**: consent obligation in Clinical Trial Agreements

- https://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/1671330
- **5. Controllership in Trial-Related Processing Operations**
  (...) On the other hand, it **should be pointed out that the individual trial centre is not under the sponsor´s control** – i.e., it accepts the protocol and agrees on its contents with the sponsor, including the wording to be used for obtaining the patients´ informed consent in line with the opinion rendered by the relevant ethics committee. The centre carries out the trial autonomously – albeit in compliance with the applicable protocol, the standard operational procedures, and the sponsor´s guidelines; additionally, the centre avails itself of collaborators considered to be suitable in carrying out the trial and is responsible for their work. The **centre provides the information notices to patients and obtains their consent as also related to processing of the data concerning them; it allows the sponsor´s collaborators to access the patients´ original medical documents to perform monitoring activities; and it handles and is responsible for the safekeeping of those documents.**
- Based on the information gathered also following the inspections performed so far, it **appears that the responsibilities vested in the individual trial centres and sponsors are different as regards clinical trials** – accordingly, **they should be regarded as either separate data controllers or joint data controllers (....)**

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Spain

- DPA: data protection consent embedded in the consent to participate in the trial or art. 9.2.j)

- Health Authorities and EthComs: notice for ongoing trials and based on the new items under art. 13 GDPR (as compared to art. 10 Dir. 95/46/EC) imposed to new clinical trials

- *some* EthComs: OK to shift legal grounds BUT following sentence needs to be included: “If you withdraw consent for the processing of your personal data, (…)”

- *GDPR Implementation: Obligation for EthComs to appoint a DPO*

NL- CCMO has spoken: consent

Centrale Commissie Mensgebonden Onderzoek

- CCMO template ("*enough said*")
  - *"patient friendly template" - "Section 10- Use and storage of data and bodily material" is MANDATORY*
  - *Data Subject Rights? (link to website)*
  - *Legal mechanism for transfer?*
  - *Sponsor DPO contact details*

EUCOM: no consent (arts. 6+9) – Feb 2018

EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medical products: quality, safety, innovation

Legal basis for personal data processing in case of clinical trials

After the discussions and consultation with other Commission services it was concluded that a legal basis for the processing of personal data gathered in the context of clinical trials for the purposes defined in the trial protocol is not consent (Article 6(1)(a) in conjunction with Article 9(2)(a) of the GDPR) but the provisions of law itself (Article 6(1)(c) in conjunction with article 9(2)(j) or (i)) of the GDPR.

Although the informed consent is the fundamental condition under which a person can be included into a clinical trial, the data processing which results from that inclusion is defined by the provision of legislation. The sponsor is legally obliged to:

Therefore, a person who consents to enrol in a trial assumes that his/her personal data will be processed for the purposes and in the conditions **defined by the legislation.**

However, if a sponsor would like to use the data gathered for any other purposes than the one defined by the legislation (e.g. presenting individual patients case during a conference) a **specific consent for data processing should be sought**. The same applies when allowing access to the individual patients forms by third country inspectors.

edpb

European Data Protection Board

Opinion of the Board (Art. 70.1.b)

Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b))

Adopted on 23 January 2019

EDPB Interplay between GDPR and CTR

- Art 6(1)(c): Compliance with a legal obligation + 9(2)(i) public interest in the area of public health
  - Safety reporting
  - Archiving CTMF + medical files
  - Disclosure of clinical trial data to NCAs
- For Research Activities
  - Consent: Not favored and caution!
    - CTR consent ≠ GDPR consent
    - Freely given? (imbalance of power)
  - Public interest- Art 6(1)(e) + 9(2)(i) or 9(2)(j) scientific purposes in accordance with art 89(1)
  - Legitimate interest – Art 6(1)(f) + idem
- Further processing
  - Presumption of compatibility – Art 5(1)(b) in connection with Art 89
  - In some cases, another specific legal ground would be needed

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EFPIA (DPWG)

- Multiple Opinion papers/Subgroups
  - Legal grounds
  - Controllership
  - Safeguards framework
  - Anonymisation practices
  - Data sharing and observational studies
  - White Paper on RWE

- International Transfers sub-group
- IMI-follow up
- Workshops
  - CIPL + Future of Privacy Forum (October 22, 2018)
- Monitoring and Mapping- implementation tracker
- Think Tanks + responses to official docs

efpia
European Federation of Pharmaceutical Industries and Associations

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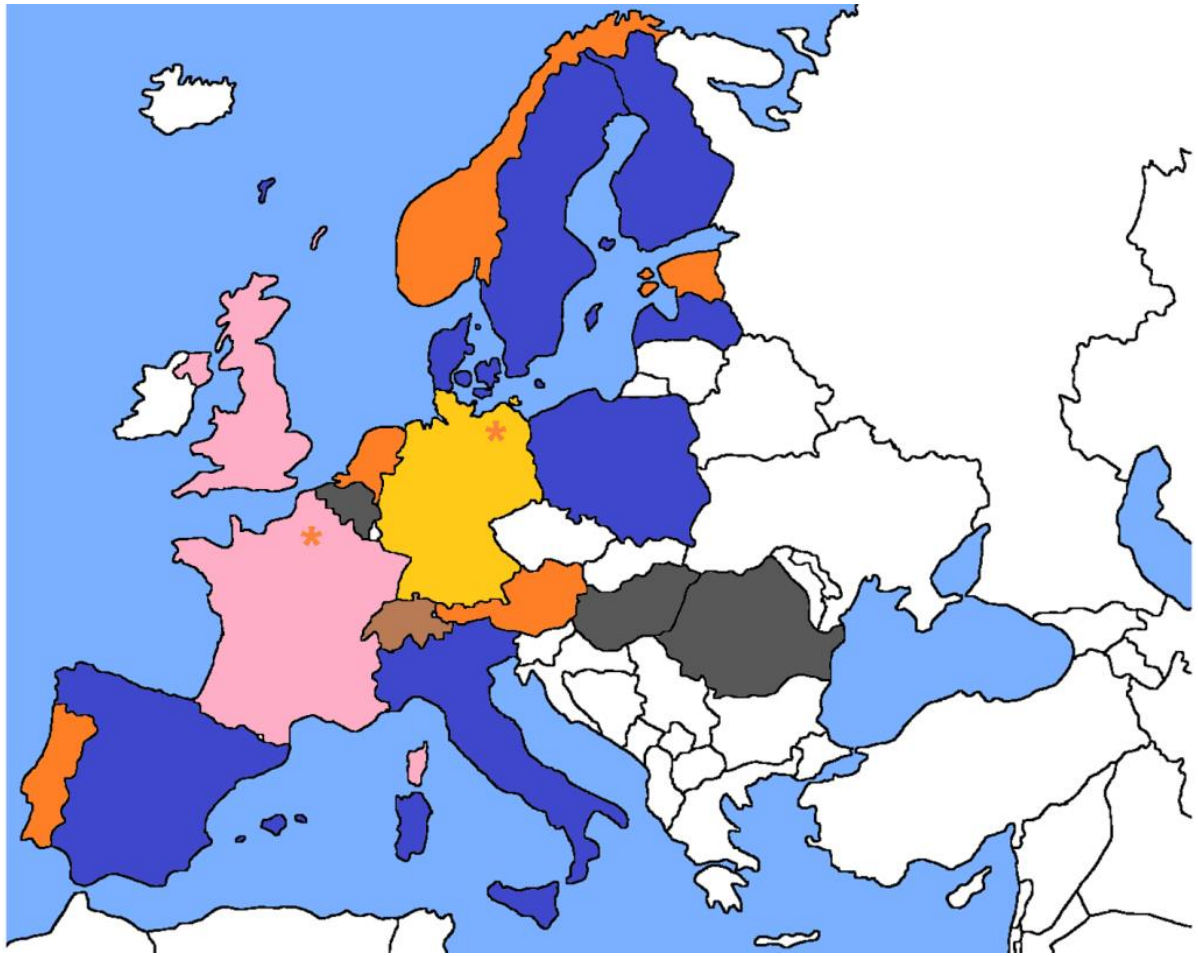
P.A.G.E. Privacy Accountability Governance Enhancement

SO WHERE ARE WE?

INFORMAL SURVEY
Legal basis for processing clinical trial data



- Art. 9 No. 2(a) – Consent to process special categories of data
- Art. 9 No 2(g) – Public Interest based on EU/local law + Clinical trial legislation
- Art. 6 No. 1(a) – Consent
- Art. 6 No 1(f) + Art. 9 – Legitimate interests + some sub-section of Art. 9
- Art. 9 No 2(j) – Necessary for scientific research purposes
- No designation made / no answer given

***Asterisk designates a differing primary opinion within a country**

Answers reflect local experiences and observations and are no legal opinion.

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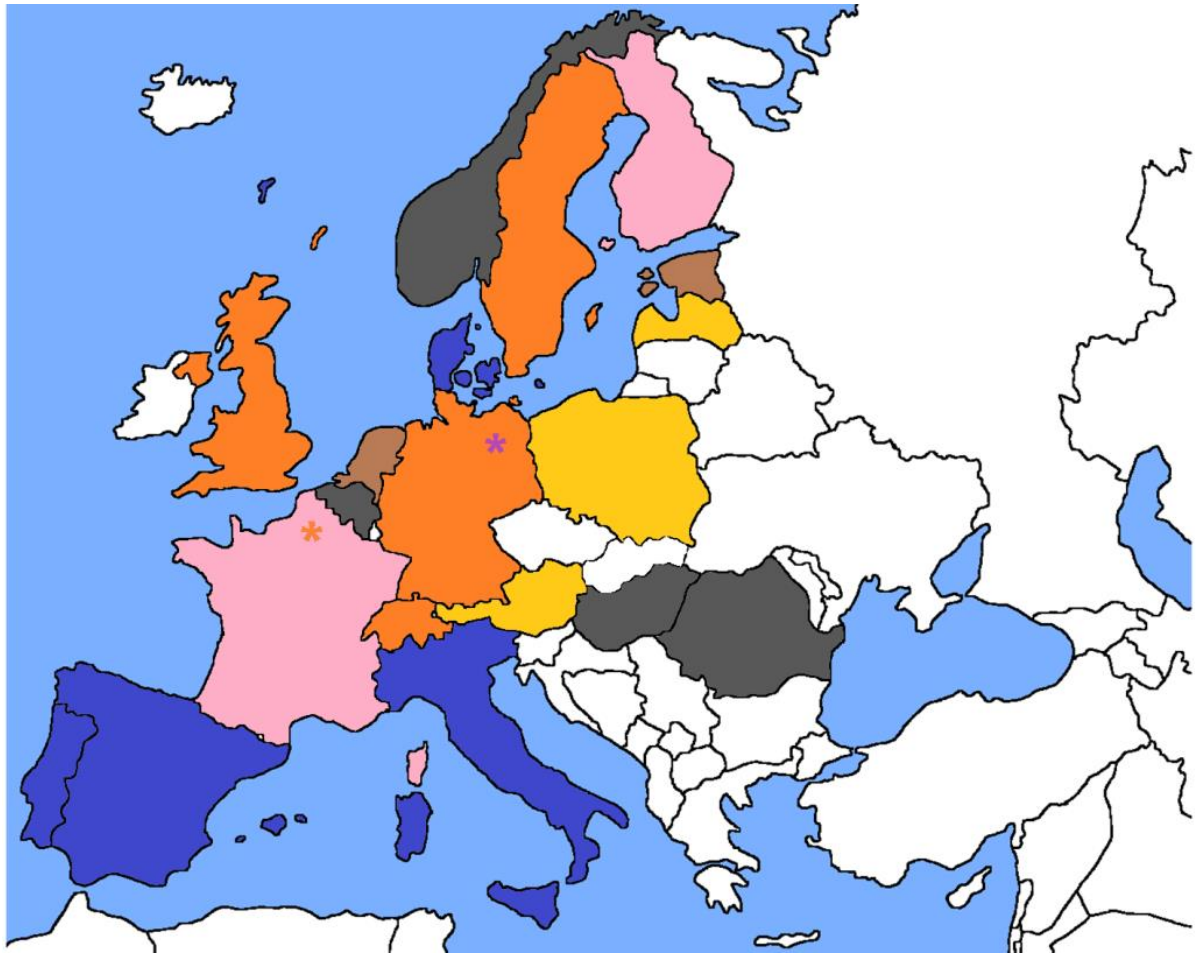
P.A.G.E. Privacy Accountability Governance Enhancement

INFORMAL SURVEY
Roles of the parties in clinical trials



- Global Sponsor = Controller, Site = Controller
- Global Sponsor = Controller, Site = Processor
- Local representative of Sponsor = Controller, Site = Controller
- Local representative of Sponsor = Controller, Site = Processor
- Local representative of Sponsor, Site = Joint Controllers
- Global Sponsor, Site = Joint Controllers
- No designation made / no answer given

***Asterisk designates a differing primary opinion within a country**

Answers reflect local experiences and observations and are no legal opinion.

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P.A.G.E. Privacy Accountability Governance Enhancement

THIS WAY
THIS WAY
THIS WAY
THIS WAY
THIS WAY
THIS WAY
THIS WAY
THIS WAY

One more thing...

Cognitive Dissonance

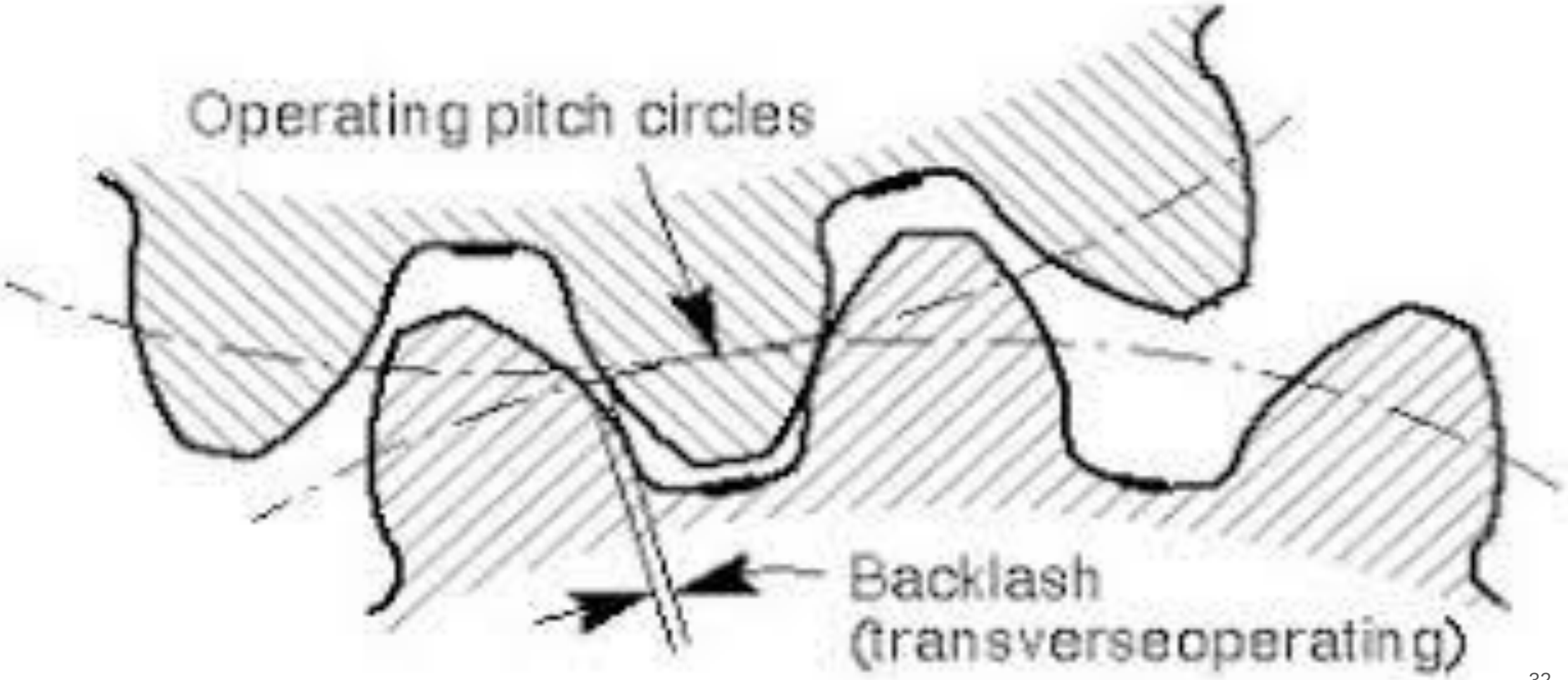
"Sometimes people hold a core belief that is very strong.

When they are presented with evidence that works agains
that belief, the new evidence cannot be accepted.

It would create a feeling that is extremely uncomfortable,
called cognitive dissonance.

And because it is so important to protect the core belief,
they will rationalize, ignore and even deny anything that
doesn't fit in with the core belief."

“Backlash effect”



Core belief(s): consent

- **The concept of informed consent is embedded in the principles of numerous codes, conventions and regulations applicable to Scientific Research:**
- Nuremberg Code (1947)
- The Declaration of Helsinki (1964)
- The Belmont Report (1979)
- CIOMS guidelines (1982 amended in 2002)
- GCP Guidelines developed by the ICH (1996)

- *Directive 95/46/EC - arts 7 and 8 (consent for processing special categories of data)*

Consent under GDPR

- **New paradigm of consent**: Article 4(11), 6 + 9 in connection to art. 7 (Conditions for consent) and recitals 32, 33, 42 and 43
  - Freely given
  - Specific (per purpose)
  - Informed (clear and plain language)
  - Unambigous + clear affirmative action

  - "Free" implies a real choice by the data subject – **no precondition of a service**
    - **NO DETRIMENT TO DATA SUBJECT if refusal to give consent or withdrawal of consent**

  - **No imbalance between the controller and the data subject**; e.g. employer-employee (sponsor-patient?)
- **GDPR consent ≠ 70+ years of the "other" consent(s)**

Final remarks

- **Why the issue of legal basis is relevant?**
- It must be mentioned to the patients in a clear manner
- It has an impact on the individual rights: portability, objection and consent withdrawal

- **Why the issue of the roles of the parties is relevant?**
- Contracts need to reflect it accurately; who is responsable for what
- Art. 28 obligations need to be in writing

- **Increased lack of harmonization post GDPR harms research (EMA dixit):**
- How to manage a pan-European study consistently and cost-effectively?
- Some EthComs are acting as DPAs?
- Some DPAs or Health Authorities are acting as legislators?

"What if we don't change at all ...
and something magical just happens?"

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PRIVACY ACCOUNTABILITY GOVERNANCE ENHANCEMENT

PCMG
GDPR: Mapping stakeholders
Copenhagen, April 2, 2019