Mini Summit IV: Advanced Issues in Transparency and Disclosure - Research and Clinical Trials Update

KANTAR HEALTH

Catalysts driving successful decisions in life sciences

Dr. Jessica Santos
Global Compliance and Quality Director
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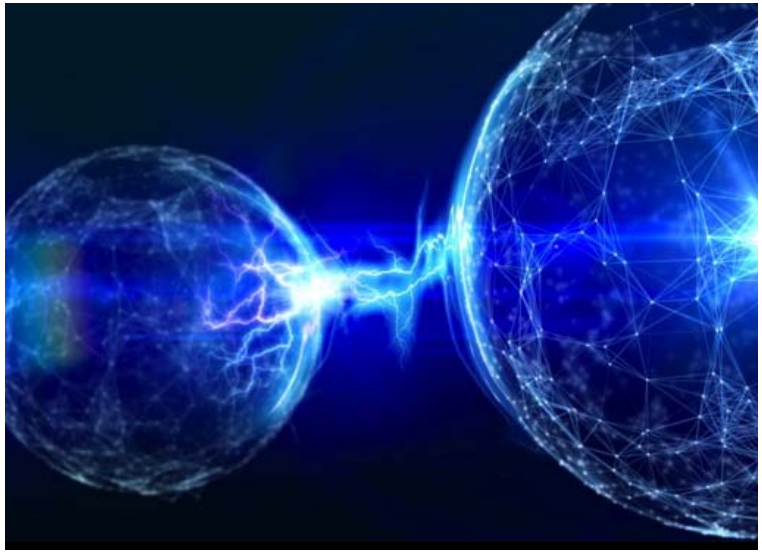
Meaning of Pharma/Life Science

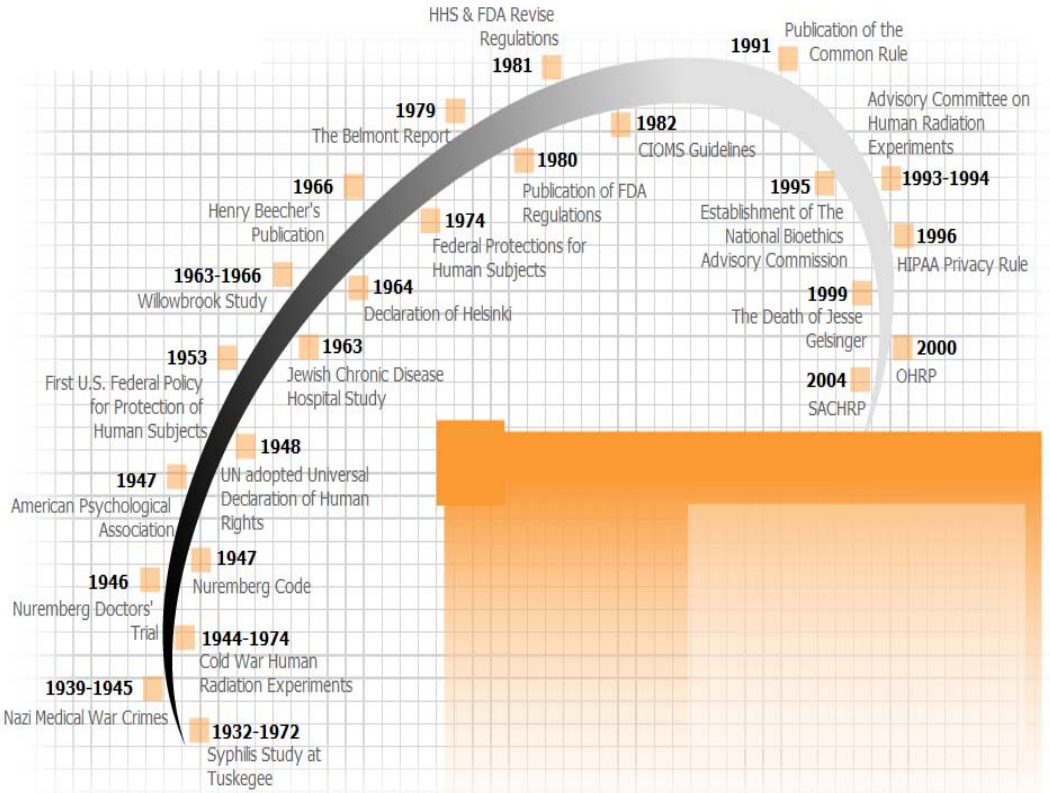
- **Medical scientific advancement**
- **Saving lives, improving quality of lives**



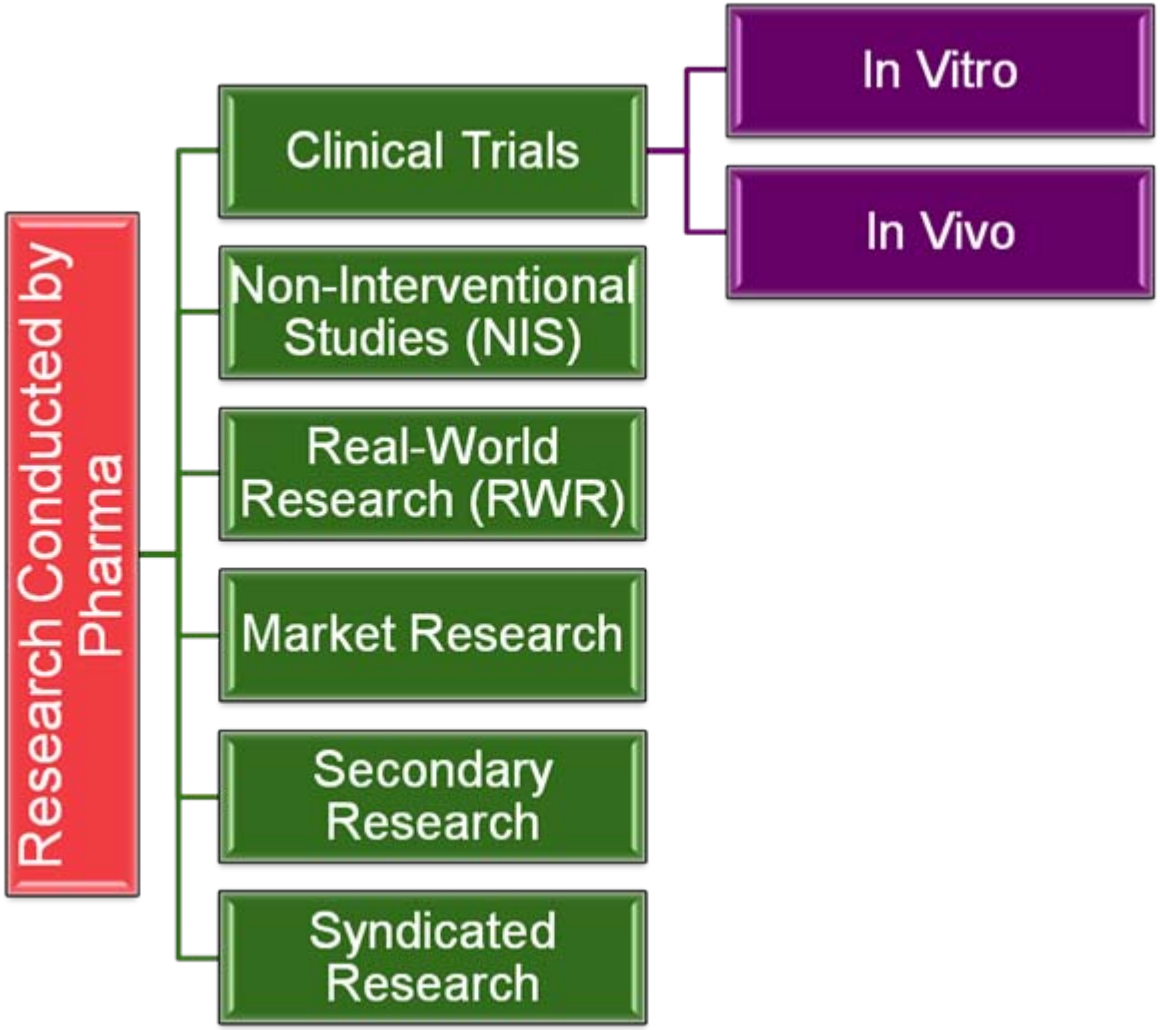
We need research.

Medical Research Involving Human Subjects

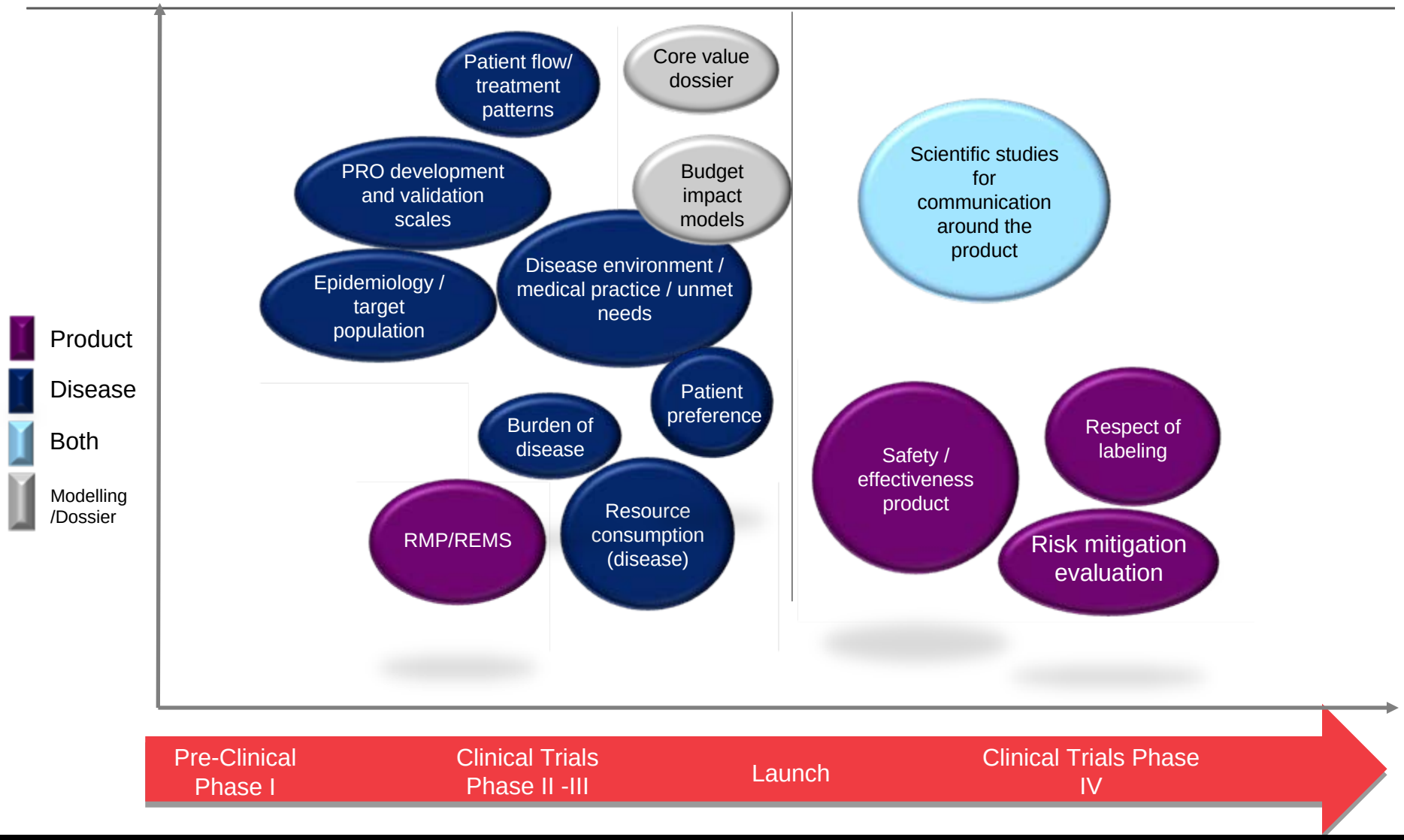
- For **medical** purposes
- As such, the relationship between investigators and human subjects is critical and should be based on **honesty**, **trust** and **respect**



What Research?



Research Lifecycle



Transparency and Disclosure

- Interaction with HCPs
- Transfer of value to HCPs
- Pharma company aware of the HCPs' identities

Transparency and Disclosure

- Most research types will involve HCPs, but via different means

Clinical Research – GCP

- A contract exists (bipartite or tripartite) between sponsor and research site and/or CRO.
- Identities of participating HCPs (investigators) is fully transparent (protocol, study plan, data management).
- Transfer of value
  - To the sites
  - To individual investigators
- Clinical trials can last years and change of personnel often happen.

Market Research

- Majority of the market research studies are double blind
  - Participants are not aware of the sponsor company neither does sponsor company aware of the individual participants' identity.
  - Hence, most market research studies are exempted (ref. EFPIA, EphMRA, CASRO, PMRG, etc.).
- Exception
  - Qualitative in-depth interview conducted by the sponsor – Yes
  - Qualitative focus group observed by sponsor inadvertently aware
  - Adverse events reporting

NIS/RWR – GPP or GEP

- May or may not involve HCP **directly**
- Sponsor may or may not be aware of the identity of the HCPs in the study.
- HCPs may or may not aware the identity of the sponsor.
- CRO/agencies typically handle HCP contact details.
- Data provided from CRO/agency to the sponsor most likely to be aggregated, but can be individual.
- If sponsor is not aware of the HCPs' identity, there is no need to report.

Secondary Data Research

- Where?
  - Data is collected from secondary source, e.g., public domain, academic publications, licensed data source, or agencies' propriety data assets.
- Who?
  - Data is often collected via agency but can be a combination between sponsor and agency.
- How?
  - Data mining, data pending, big data, database merging and forecasting
- What?
  - Very limited direct contact with HCPs (except ask for copyright permission or opinion), and almost no transfer of value

Syndicated Research

- Sponsored by research agencies
- Aim be sold to multiple end users
- Agency and HCPs are often not aware of the sponsor at the point of data collection.
- Transfer of value is common to encourage participation.
- Data is usually presented in aggregated format, but can be narrowed down to individual level with statistical means.
- At the point of purchase syndicated data
  - Some pharma demand to know the identity of the HCPs for reporting purpose – there was no consent in place.

Impact on Privacy Legislation in Disclosure

- HCPs might not be aware that their details will be used for disclosure when they participate a research study.
- Explicit informed consent is required if met disclosure requirement.
- Consent **cannot** be retrospective or held as a condition of payment (e.g., after clinical trial is closed, HCP is informed their details will be disclosed or no payment to their work will be paid).
- This will influence participation rate if not communicated properly.
- Payment disclosure can be made on an aggregated level or anonymized.

Dr. Jessica Santos
Global Compliance Director

Kantar Health: The catalyst for successful decision making in the life sciences industry

T: +44 (0)1372 825 329 M +44 (0)7768448528

jessica.santos@kantarhealth.com

www.kantarhealth.com

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