Patient Perspective on Renovation of ICH Guideline on GCP in Clinical Trials

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ICH E6 Renovation

- Need for renovation arises from changes in the environment of clinical research – including impact of new technologies – big data, new trial designs, proportionate risk-based approach, use of digital tools…

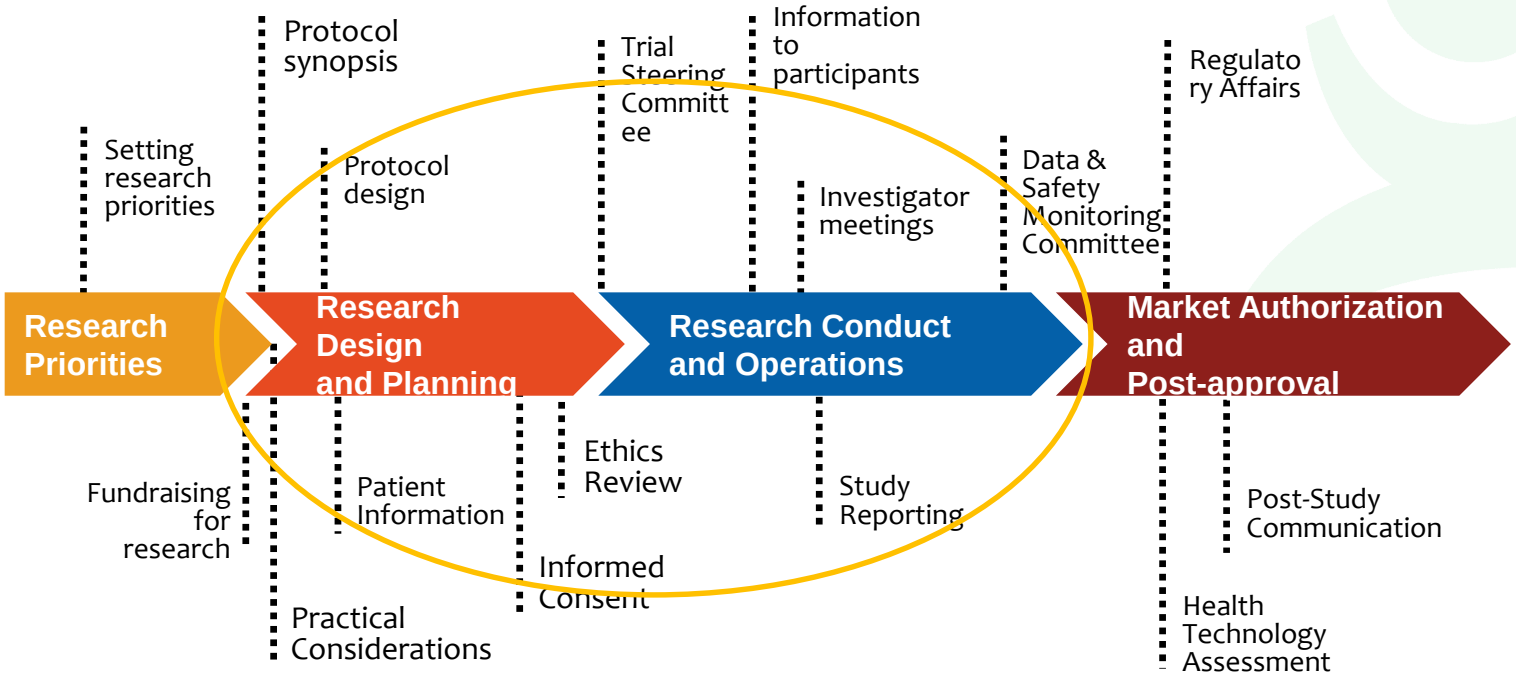
- Fundamental ethical principles should be respected while adapting to new realities

- Patient role has evolved since guidelines were last revised
- Opportunity to contribute to more patient-centred trials

- Important areas to consider include Informed consent and patient involvement

Scope of ICH E6

One piece in the puzzle of research & development of new therapies



"Impact of patient involvement is greater, the earlier it happens"

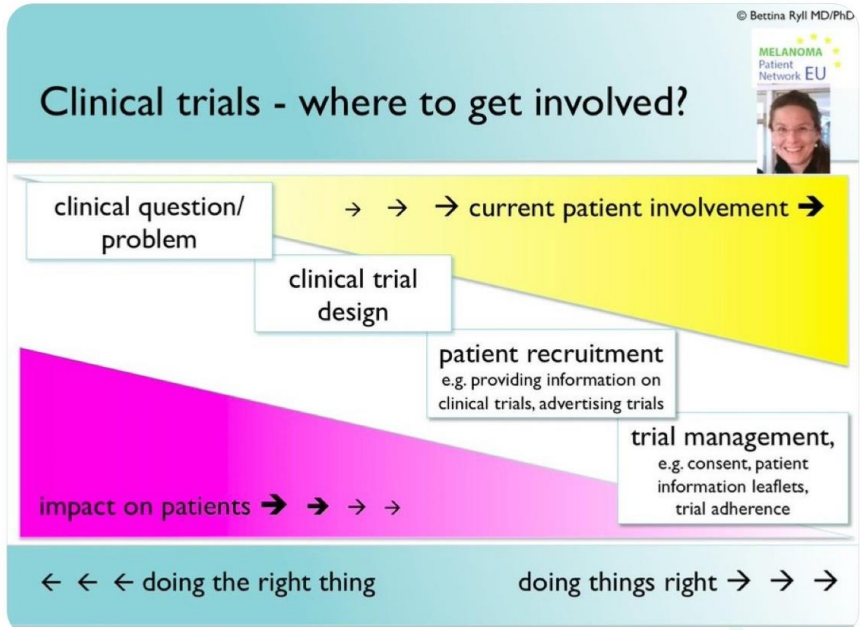
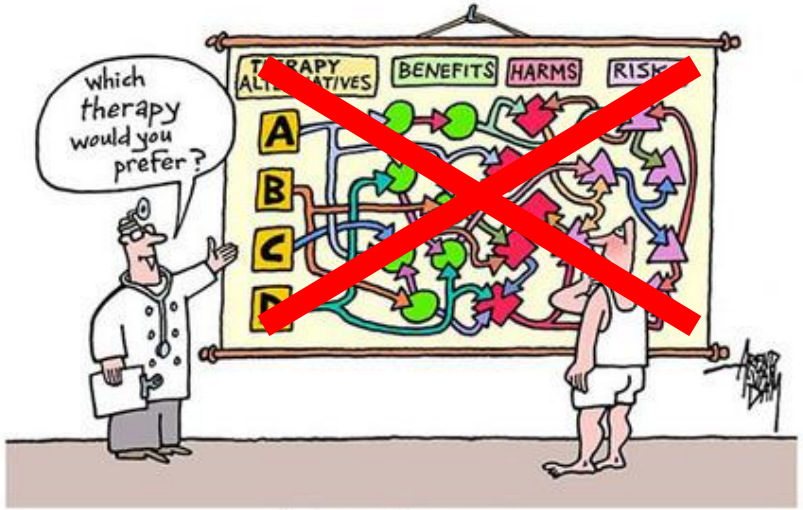


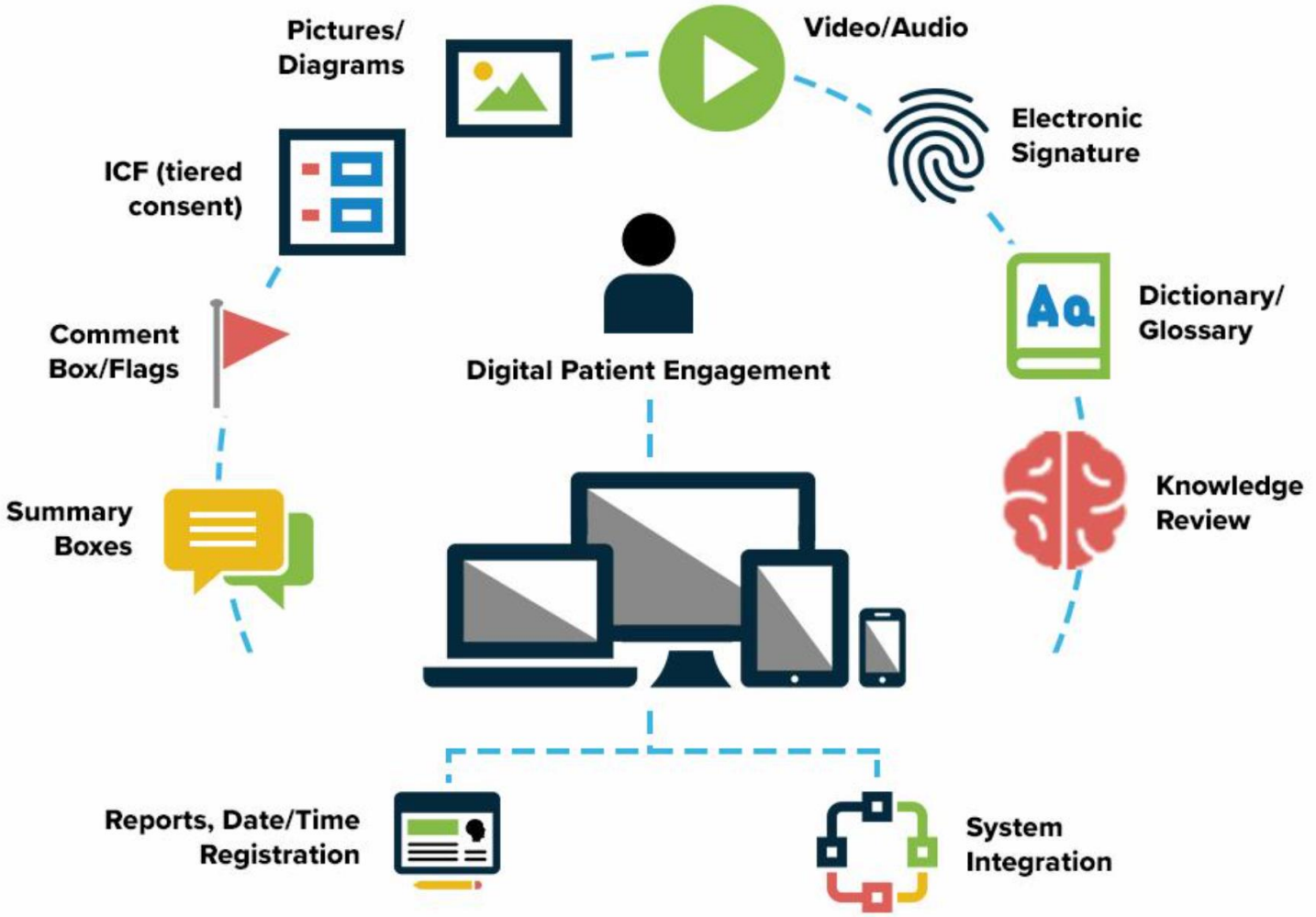
Image courtesy of Bettina Ryll

Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap. Geissler, Ryll, Leto, Uhlenhopp, Therapeutic Innovation & Regulatory Science (2017),
doi: 10.1177/2168479017706405, and at www.eupati.eu

Informed consent – new opportunities



informed consent



Source: eConsent: Implementation Guidance (Transcelerate Biopharma Inc., 2017)

Patient involvement – more relevant research

Need to create a new section to deal with aspects of patient involvement

- Patients provide the data and take the risks, benefit from the results
- Legitimacy, transparency and accountability
- Patient involvement leads to better, more relevant research results, e.g.

  - Alignment of innovation with real unmet needs
  - Design of trials, e.g. endpoints that are relevant, QOL and PROMS
  - Patient priorities in terms of benefits and risks
  - Inclusion & exclusion criteria that reflect “real world”
  - Better quality of information material
  - Trial’s practical arrangements less burdensome - fewer drop-outs, better adherence - better data
  - Ethical aspects of the trial
  - Challenging researchers’ assumptions, adding new knowledge, dissemination of results

Drawing from current good practices

- Inspiration and guidance from resources developed by PARADIGM and EUPATI as well as others (PFMD, Transcelerate…)
- CIOMS Working Group XI will publish a global guidance on patient involvement – should align with this
- Terminology: from “subjects” to “participants” or “volunteers”?
- Training in GCP: should it include training in involving patients?

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EUPATI European Patients‘ Academy on Therapeutic Innovation

PARADIGM Patients Active in Research and Dialogues for an Improved Generation of Medicines

CIOMS

CIOMS Working Group on Patient Involvement in Development and Safe Use of Medicines (April 2018) – WG XI

Conclusion

Partner

(Co-) Researcher

Participant

Subject

Citizen control	Degree of Citizen Power
Delegated power	
Partnership	
Placation	Degree of Tokenism
Consultation	
Informing	
Therapy	Non participation
Manipulation	

(Arnstein, 1969)

"Patient-centred"
Paternalistic

Collaborative & Partnership

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