



CDDF WORKSHOP

27 - 28 September 2021

ONLINE WORKSHOP

*Digital Tools and Artificial
Intelligence in Oncology Drug
Development*



SESSION 5: INTEGRATION OF PATIENTS IN DIGITAL TOOL TRIAL DESIGN AND DEVELOPMENT

Data Protection and Security

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Health Connect Partners





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Disclaimer

- No conflicts of interest





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Introduction

- Better integration of patients in the design and trialling of digital tools, as well as in digitally supported trials is still on a journey
- A key aspect of that journey is conformity with the GDPR and the adoption of new approaches to data collection and processing.
- New tools for better patient engagement in the execution of GDPR based duties are in development



- *Review of GDPR duties.*
- *Towards dynamic consent models*





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GDPR - the baseline for processing patient data - in trials and in care provision

THE SEVEN PRINCIPLES OF LAWFUL DATA PROCESSING

FOR SPECIFIED
AND EXPLICIT
PURPOSES

ADEQUATE,
RELEVANT AND
LIMITED

ACCURATE

STORED ONLY FOR
AS LONG AS
NECESSARY

PROCESSED
SECURELY

THE CONTROLLER
AND PROCESSOR
SHALL BE
ACCOUNTABLE

***All seven must be observed
whenever data are collected,
used or stored***





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It's all about information ...



- **Information about the trial** - objectives, methods, impact.
- **Information about the care service** - the role of the digital tool within care provision
- **Information about the data to be collected** - how it will be used, by whom, how stored, for how long
- **Information about rights** - to withdraw, to delete information, data portability



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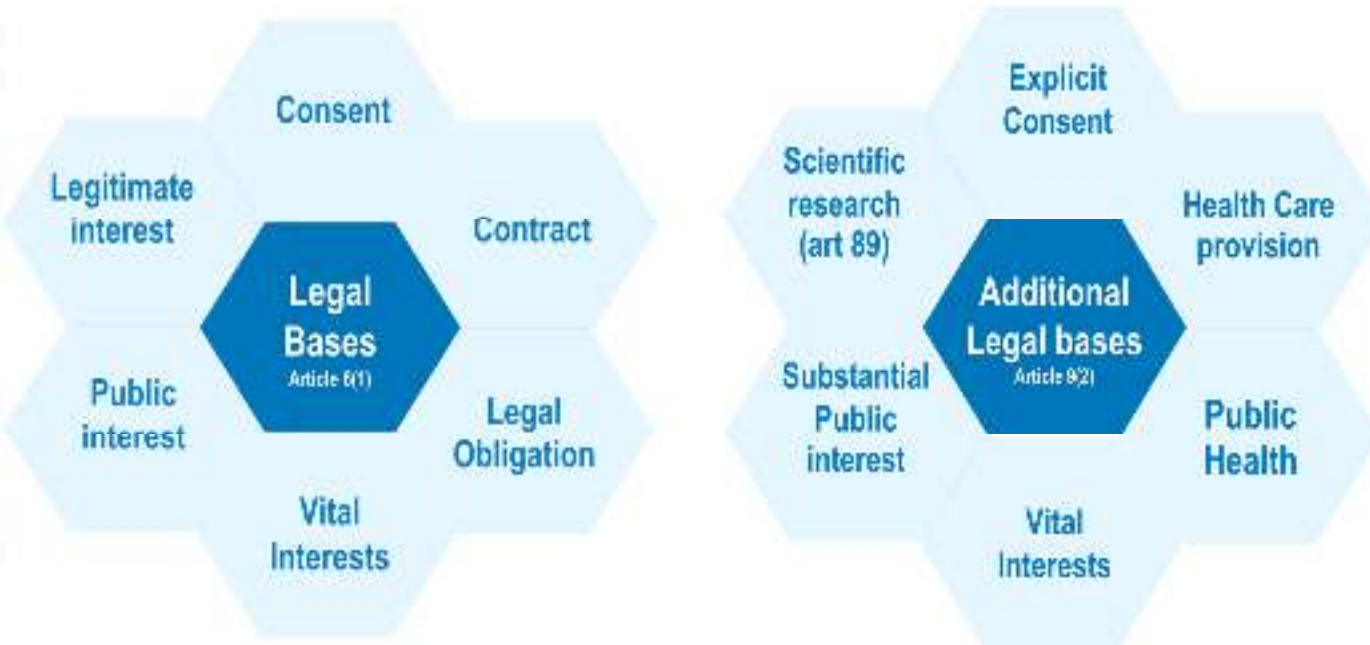
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GDPR - the baseline for digitally supported trails



Informed consent

- the base line for data process and clinical trail inclusion
- Demands adequate, accessible, appropriate information.
- Participant support and engagement



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GDPR - the baseline for digitally supported care



Legal obligation + Healthcare provision

- Consent is rarely the legal base
- Information remain an ethical duty as well as wider GDPR duty



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Towards Dynamic Consent in clinical trials and care provision



- Digital Interface
- Tailored information
- Structured patient interaction
- Management of consent authenticity
- Individual consent management
- Formalised data transfer through distributed ledger technology
- Results feedback
- Group Decision making
- Public involvement MORE THAN eConsent!





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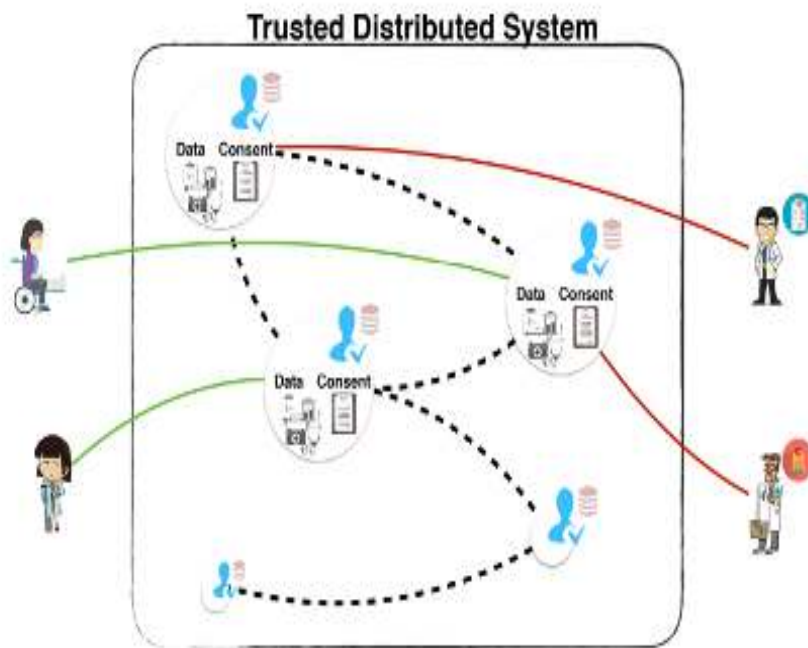
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....but we are not there yet

An
Example
- SCoDES
Project



- Regulatory recognition
- Software development and integration
- Maturing of blockchain
- Fear of 'consent fatigue'



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TRUST

- Trust remains the greatest currency
- Appropriate, targeted, used and understood information on planned use of data is a core element of forming trust
- Transparency on actual use of data and real benefits that arise from it is needed to feed and maintain trust

