PROSPECTIEF
LANDELIJK
CRC COHORT

Prospective Dutch CRC cohort
&
GDPR

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Prospective Dutch CRC cohort & GDPR

Not that much changed!

Prospective Dutch CRC cohort

What and Why

- Only a small minority of patients participate in studies
- Not possible to extrapolate data of this non-representative group to the total patient population
- High quality data and material of a representative cohort of patients is needed to achieve better outcomes

Stage I, II, III, IV colorectal cancer

Observational:

- Clinical data
- Tissue
- Blood
- PROMs

KNL Integraal kankercentrum Nederland

health RI research infrastructure

BBMRI.nl

profiles

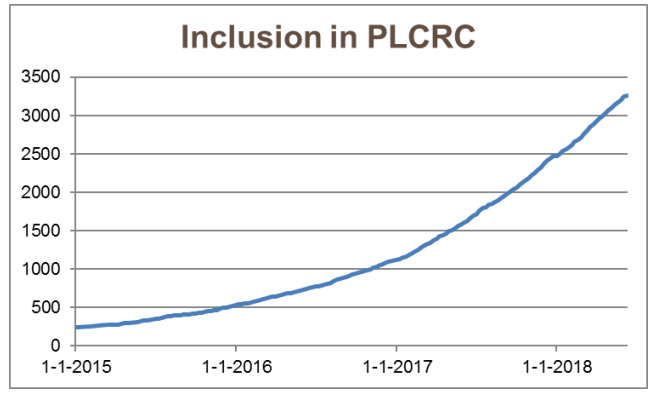
Interventional:

cohort multiple Randomized Controlled Trial (cmRCT)

PLCRC is a nation-wide cohort study to facilitate scientific research

Medical Research Involving Human Subjects Act applies (WMO- plichtig)

Current status PLCRC



We heard many questions, however…

GDPR permits data processing for scientific research, provided that the privacy and rights of the subjects are guaranteed.

In general:
· Transparency is required;
· Clear information to those involved about the use of the (personal) data;

Changes in PLCRC because of GDPR

- Amendment of the patient informaton leaflet
- Two factor authentication webbased applications
- Privacy statement website
- Many questions and discussions….

Should patients give a new informed consent for their participation in a clinical study?

- Not necessary to ask patients who participate / have participated in a clinical study a new informed consent for the processing of their personal data (: 're-consent' not necessary).

Who can inform the patient and ask for informed consent?

- Research nurses can screen for eligible patients
- Other HCPs than the treating physician can inform the patient about a study
  - After signing the delegation log!
- Registration of identifiable data needs to be mentioned in IC

Which data can be collected?

- Registration of BSN is not allowed for scientific research

  Only government organizations and other organisations mentioned in a law are allowed to use a citizen service number (BSN).
- More and more hospitals do not allow retrospective collection of clinical data without informed consent

And further:

- GDPR does **not** apply to deceased persons:

  Further processing of research data already collected, does not lead to privacy objections. Deceased persons are no longer natural persons.

- There can be differences between European member states:

  On specific points, GDPR offers member states the opportunity to define further details

How to give access to data and aplications?

- Two-factor authentication, necessary for HCPs and patients?

- Do not share more (identifiable) data than necessary!
  - No address in a digital invitation
  - No name in an invitation, but “dear participant”