The impact of the Data Protection on the lives of European Cancer Patients – informed consent, biobanks and mHealth
ECPC: "Nothing about us, without us"

- Representing 406 cancer patient groups in 46 countries
- All cancers – common and rare
- Run and governed by patients
- Promoting **timely access** to appropriate prevention, screening, early diagnosis, treatment and care for all cancer patients
- **Reducing disparity** and inequity across the EU
- Encouraging the **advance of cancer research & innovation**
- Increasing cancer patients' **influence** over European health and **research policy**
ECPC represents cancer patients within

- European Commission
  - Joint Action on Cancer Control - CanCon
  - Joint Action on Rare Cancer - JARC
  - Expert Group on Cancer Control
- European Medicines Agency
  - Patients’ and Consumers’ Working Party
- mHealth
  - WG on mHealth apps assessment guidelines
  - Contributing to the Code of Conduct mHealth apps privacy
Safeguarding the future of Clinical research
General Data Protection Regulation
A communication problem?

Public concerns about privacy
= more regulation

More regulation
= burdensome clinical research

Burdensome clinical research
= late (or no) access to new treatments

No innovation
Risks of the New Data Protection Regulation
ECPC and Cancer Community together

• Position paper coordinated by ESMO in 2014
• It represented the voice of the cancer community
  • ESMO, ECCO, EORTC, ESSO, SIOPE, EMEA Society for Biopreservation and Biobanking
  • Broad consent
  • Anonymization and use for historic record
• ECPC had important role, bringing the voice of cancer patients
  • Meeting with Italian Under Secretary for Justice in 2015

Final result: ECPC’s demands were integrated in final version of GDPR
After the GDPR
Solving key issues

• Informed consent
• Biobanks
• mHealth
• Informed consent
• Biobanks
• mHealth
Informed consent

Scientific community has to establish a dialogue to inform and empower the patient on the advantages related to the donation.
Informed consent

• **Broad, withdrawable, one time consent**
• Equitable collection
• Derogation from broad consent only for epidemiological data and registries
• **Reciprocity**: patients should be made aware of developments arising from use of their data
• Linkage of data and anonymity: we understand power of big data, but anonymity is key to TRUST
Creating an alliance with patients: Towards a new informed consent

• Patients should have control over their personal data related to biologic sample => anonymization of patients data shall be performed when requested by the patient

BUT

• THE DONATION IS IRREVERSIBLE
  The biological sample SHALL NOT be destroyed even if the consent to use patients’ personal data is revoked:
  • If biological sample is not attached to the data, patients’ privacy is fully respected
  • Destroying the sample will hamper the value of data stored by the biobanks
• Informed consent

• Biobanks

• mHealth
Biobanks

Interior of one of 15 of the large walk-in freezers in the DoDSR, Wikipedia.org
Biobanks and Patients
A mutually beneficial partnership

• Biobanks
  • Crucial role in clinical research, including DNA sequencing/diagnostics
  • There is no safer place to store information on patients
  • BBMRI – ERIC is the future: added value of European aggregated data

• Patients
  • Benefit of cancer research ran on biobanks data
  • Patients have strong political voice
  • Biobanks would not exist without patients’ donations
Biobanking: FAQs

Dr. Peter Riegman, Dr Maria Grazia Daidone, Jacqueline Hall (EORTC) in collaboration with EPC Vice-President Kalliopi Christoforidou and Projects Officer Kalliopi Christoforidou
• Informed consent

• Biobanks

• mHealth
mHealth Cardiograph app running on Nexus 4, African Health Matters Newsletter, CC BY-SA 2.0
What cancer patients expect from mHealth?

Better cancer patient experience

• Better outcome
  • Patients mobility

• Better quality of life
  • Home care / Self care

• Better information
  • Doctor/patient
  • Patient/legislator
  • Access to patient records!

• Better survivorship
  • Transition from intensive care to healthcare follow-up
  • Rehabilitation services
  • Return to work
How is mHealth used in cancer today?

- It is employed only for limited uses and during limited phases of the care process
  - mHealth is mainly used for **self-management** activities carried out by cancer patients **during treatment**
    - rarely used for decision-making and follow-up activities
  - mHealth runs mostly on **phone** and **tablets**
    - Increasing role of remote monitoring devices

Usability – Patients’ literacy

• Hardware limitations
  • Not all patients are used to smartphones/tablets
  • Limited input capabilities

• Design limitation
  • Simplicity is key!
    • Simple high contrast colors
    • Non pop-ups
    • Clear navigation
    • Simple content organization
    • Include images and videos!
    • Training for new users (patients)

Sources
Large & small developers

Motivation is good…

• 46% of mHealth app publishers do it also to help others

… but it is not enough!

• 50% of mHealth app publishers have not released more than 2 mHealth apps
• only 32% of publishers rely on mHealth apps’ revenues

Need for GUIDELINES to ensure that apps are credible

Source: research2guidance mHealth App Developer Economics survey 2014
After the GDPR
Solving key issues

• Informed consent

• Biobanks

• mHealth