NeuroArtP3 management model: how to balance scientific and GDPR requirements

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Artificial intelligence of imaging and clinical neurological data for predictive, preventive and personalized (3P) medicine

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NeuroArt P3

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Work Package and Italian Region	Centre	Role in NeuroArtP3	Disease under study in NeuroArtP3
WP1 - Liguria	IRCCS Ospedale Policlinico San Martino	Clinic	AD, PD, SM, SLA
WP2 - Trento	• Azienda Provinciale dei Servizi Sanitari • Fondazione Bruno Kessler	Clinic Computational	PD, SM All
WP3 - Milan	IRCCS Ospedale San Raffaele	Clinic	Adult Glioma
WP4 - Liguria	Istituto Giannina Gaslini	Clinic	Pediatric Glioma
WP5 - Florence	Fondazione Don Carlo Gnocchi	Clinic	SM
WP6 - Liguria	Liscomp LAB - Unige	Computational	All

5 Multicenter Study – disease driven -> submitted to CET for ethical approval
Retrospective/prospective observational studies

NeuroArtP3 Case Report Form (CRF)

- Observational studies -> the clinical practice of patients is not modified (GCP, minimization)
- Objective: generate artificial intelligence models predicting the 3-year clinical course

1) Patient History - contains demographic and general information

- Year of diagnosis, sex, writing hand
- Education level, main occupation
- Caffeine consumption, cigarette smoking, alcohol abuse
- Family history of program-related diseases, comorbidities at diagnosis

2) Essential Variables - collected at every visit (baseline and the following 3 annual follow-ups):

- Disease severity
- Pharmacological history
- Motor and cognitive aspects
- Non-motor behavioral symptoms
- Magnetic Resonance Imaging (MRI)

3) Supplementary Variables - collected at the baseline visit:

- Blood analysis, immunophenotyping
- Genetic mutation analysis
- Pregnancies, oral contraceptives
- Nuclear diagnostic imaging (PET, DaT/SPECT, MIBG)

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General Data Protection Regulation (GDPR) UE n. 2016/679

Data (art.9 GDPR):

1. Non-personal data: a particular category of data consisting of all information that cannot be linked to an “identified or identifiable” person (i.e. generated by industrial devices)

2. Personal Data: any information relating to an "identified or identifiable" physical person

↓

<u>All the information that can be traced back to a single individual</u> through their characteristics, relationships, habits, lifestyle, and so on

Personal Data – Art.9 GDPR

- All identifying information, from personal data to images depicting the person;
- Judicial information that can reveal the existence of certain judicial measures against the person;
- Data related to electronic communications via phone or internet, such as an IP address;
- Data that allows the geolocation of a person and from which it is possible to understand where they have been, when, and sometimes even with whom
- All data previously defined "sensitive data"(d.lgs 196/2003), therefore subject to special protection

↓

Particular Data (Art.35 GDPR)

Particular Data – Art.35 GDPR

1. Racial or ethnic origin;
2. Political opinions, religious or philosophical beliefs;
3. Trade union membership;
4. **Data concerning health** or a person's sex life or sexual orientation;
5. **Genetic and biometric data** intended to uniquely identify a natural person

Particular (ex-sensitive) data should not always be processed. Is this always true? It depends

Data concerning health (Art.35 GDPR) ->

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Privacy Impact Assessment (PIA)

- to outline the risks associated with data processing and the corresponding security measures

the result was positive

Data Processing Agreement (DPA)

- to outline the relationship between the parties (WPs),thus qualifying:
  - all clinical WPs as **Autonomous Data Controller**
  - the two computational centers as **Data Processors**

Material Transfer Agreement (MTA)

- to define the exchange of biological material

Data collection:

- all data recoded were previously **pseudonymized**
- eCRF: all data were collected in **compliant software** (REDCap; X-NAT)

Legal basis

Notice and patient **informed consent** for the processing of personal data

- Legal basis

  Notice and patient **informed consent** for the *processing of personal data*

- Ethical basis

  Notice and patient **informed consent** for the *participation in the study*

Nuremberg trials 1945.11.20

The patient has the right to be informed
The patient has the right to give his consent
The patient has the right to revoke his consent

Thank you for your attention!

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