Biological Samples in clinical trials
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Clinical protocol

Samples are well defined in the clinical protocol:

• What to collect
• When
• How many times
• How much
• For what

• Minimizing discomfort for subject (volume and frequency)
• Maximize use of any sample
Informed Consent Form

In the ICF must be indicated

- Which samples are collected
- For which purpose
- Where are they sent and stored
- How long they are stored

- Lab can only analyse sample for the purposes indicated in the consent form
In the Clinical Trial Application it is indicated which laboratory(ies) will received the samples

Any new lab involved in the study for analysis needs to be recorded
Contracts

Contract in place with any lab receiving samples

Agree on:
  - which analysis
  - what sample receive
  - sample management
  - how many
  - how samples will be shipped
  - frequency of shipment
  - turnaround of results
  - retest
  - destruction

Privacy rules
Samples in clinical trials

Everything shall be defined in the study set up phase
  Pre-planning
  Consistency across documents

Study is approved by EC and AIFA

Little flexibility
  Any significant change shall be submitted to competent authorities for approval
Samples in clinical trials

Sample may be managed and processed differently according to planned test (whole blood, plasma, serum, pellets)

Samples must be tracked from collection till analysis and destruction.

Sample must be identifiable.
Samples in clinical trials

Coded / Pseudoanounimised
No subject personal or medical information

• Study number
• Subject number
• Date and time
• Timepoint
• Matrix
• Sometimes age and sex (if lab ranges differs based on them)
Samples in clinical trials

In most cases subjects are taking either

- an experimental drug
- a placebo
- a comparator

and this information is not known

Each subject has different samples at different timepoints

1 predose
Samples in clinical trials

- Residual
  - Normally destroyed
  - Can be used for additional tests if indicated
- Back up
  - Kept till test performed, results accepted, then destroyed
  - Can be used for additional tests if indicated
- Retention
  - Stored for regulatory purposes
  - No additional use
- For additional research
  - Collected and used for additional tests if indicated
Biological bank

Site / institution biological bank
- To store samples and make them available for internal research
- Coded
- The site can link them to clinical data

An external biological bank
- To store sample and make them available to those who request them
- Coded? Anonymous?
- No link to clinical data
- Limited information provided (disease age sex)?
Who owns the sample

The patient
  can consent to send sample, conduct additional research, share data etc

The site
  responsible for the sample management, can use it as per protocol and consent

The sponsor
  although doesn’t own the samples, can block their distribution to other sites or the conduct of additional research
Clinical trial and biological bank

Indicate in the ICF that a sample (which one?) will be stored in BB and make available to other researchers.

Define which clinical information will be provided with the sample.

Define if the sample is anonymous or coded.

Define storage duration and destruction rules.