Towards an Automated Assistant for Clinical Investigations

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CLINICAL INVESTIGATIONS

- Before drugs can be made available to the general public, their effectiveness has to be experimentally validated.
- Normally, at the final stages, clinical investigations (CI), involving human subjects, are carried out.

KEY CONCERNS

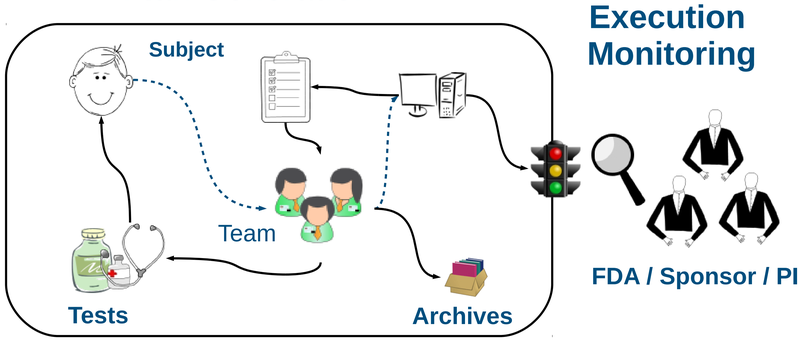
Safety of Subjects

One should avoid at all costs that the health of subjects is compromised during the tests.

Conclusive Data Collection

CIs should be carried out in order to obtain the most conclusive results/data without compromising the health of subjects.

Plan Generation



Execution Monitoring

Whenever a subject visits a HI, the staff receives from the computer assistant a plan (Plan Generation) with the actions that need to be performed.

The computer assistant can help FDA inspectors, Sponsor monitors and the Principal Investigators of HI to monitor the execution of the CI

POLICY

Regulations may be imposed by multiple governmental agencies as well as by institutional policies and protocols. Due to the complexity of both regulations and activities there is great potential for violation due to human error, misunderstanding, or even intent.

FDA Regulations

"Any adverse experience associated with the use of the drug that is both serious and unexpected; Each notification shall be made as soon as possible and *in no event later than 15 calendar days* after the sponsor's initial receipt of the information."

Protocols

Protocols are elaborated by specialists explaining how one should carry CIs, so that the most conclusive data is collected and the health of subjects is not compromised.

Pharmaceutical companies (Sponsor), clinical research organizations (CRO), health institutions (HI) and government agencies (FDA) collaborate in order to carry out CIs.

- Deviations from procedures and violations of regulations should be avoided as they may compromise both the collected data and more importantly the health of subjects.
- CIs are rigorously regulated by FDA inspectors.
- Violations may also imply heavy penalties, both financial as well as of bad PR.
- HIs with record of deviations in the past may be punished by the market and not being hired for carrying out future CIs.

- A better approach would be to have a computer assistant for CIs.
- Two possible applications (see Figure to the left), Plan Generation and Execution Monitoring.

Mathematical models

- As illustrated above, regulations and policies mention time explicitly.
- Novel models for collaborative systems subject to explicit time constraints.
- Computational complexity for the plan generation problem.

Tool Development

- Ways to translate protocols into our mathematical formalism.
- Investigate adequate human computer interfaces.

Data Management

- Formally certify that privacy policies are not violated.
- Facilitate the statistical analysis of data by building bridges to existing tools.

- Deviations from procedures and violations of regulations do occur.
- At each site it is common to have more than one on going trial, typically 5-10 trials at the same time.
- Trials take place along with normal hospital duties.
- Easy to lose track of the global view of the process.
- Therefore, there is great potential for violation due to human error, misunderstanding, or even intent.

Next Steps

- Define a language for specifying protocols that can be understood by protocol developers and at the same time implemented in our model.
- We expect this language to be based on existing standards for CIs, such as the model proposed by Clinical Data Interchange Standards Consortium.