CLINICAL TRIAL START-UP STEPS AND CONTRACT RECONCILIATION PROCEDURE

Sponsor/CRO gives information about the clinical trial to the Principal Investigator. **CRCO Start-up assistant** supports the PI, and helps in the start-up procedures.

Principal Investigator decides to participate in the clinical trial. **CRCO On-site Monitor**, and **CRCO Qualitiy Assurance Manager** help to get ready for the clinical trial's opening and support PI at the site initiation visit as well.

Sponsor/CRO starts the procedure of offical correspondence.

Sponsor/CRO contacts the **Lawyer of Clinical Research Coordination Office** at the University of Szeged, to reconciliate the Institutional Agreement.

Sponsor/CRO and the Lawyer of **CRCO** discuss the legal aspects of the Institutional Agreement via e-mail until both sides are satisfied with its content.

Sponsor/CRO sends the signed Institutional Agreement to CRCO and attach other important documents *

(The CRCO needs at least 2 copies of the Institutional Agreement)

Lawyer of CRCO checks the received Institutional Agreement, and if its content is as agreed, countersigns it.

Lawyer of CRCO towards the Institutional Agreements to the Contract Coordation Officer of CRCO.

*** Other important documents:**
- Sponsor's statement about the division of total investigational fee
- Regulatory authorities' statement of approval of the trial
- Insurance statement
- Protocol
- Informed consent form