

Clinical Trial Monitoring

The majority of the Clinical Research Associates (CRAs or monitors) at our company are MDs. By utilizing medical doctors, the overview of medical charts and the rapport with investigators is of the highest quality thereby assuring our clients that the patients included in the research trial are enrolled appropriately and their safety is of the utmost importance. Therefore, safety and data validity are ensured. The CRAs manage their sites including training site staff on protocol requirements and verifying that the clinical trial is conducted under Good Clinical Practice (GCP). CRAs conduct initiation, routine monitoring and close out visits to all sites involved in a study. All research conducted by the Russian investigators are under ICH (International Code of Harmonization) and GCP standards thereby assuring excellent data quality. In sum, our monitoring includes:

- Site Selection and Qualification in accordance with Protocol and ICH GCP requirements
- Site Initiation
- Routine site Monitoring per Monitoring Plan and Sponsor Expectation to provide high Quality of data retrieved
- Tracking of Query resolution process
- Site management
- Study logistics management
- Study Close-out

In addition, we oversee:

- Study drug and non-drug supplies logistics
- Tracking regulatory document revisions
- Tracking protocol deviations/violations
- Tracking subject progression