
CONGENIX
COMPLIANCE RELIABILITY OPPORTUNITIES
www.congenix.com
Contract
Research
Organization

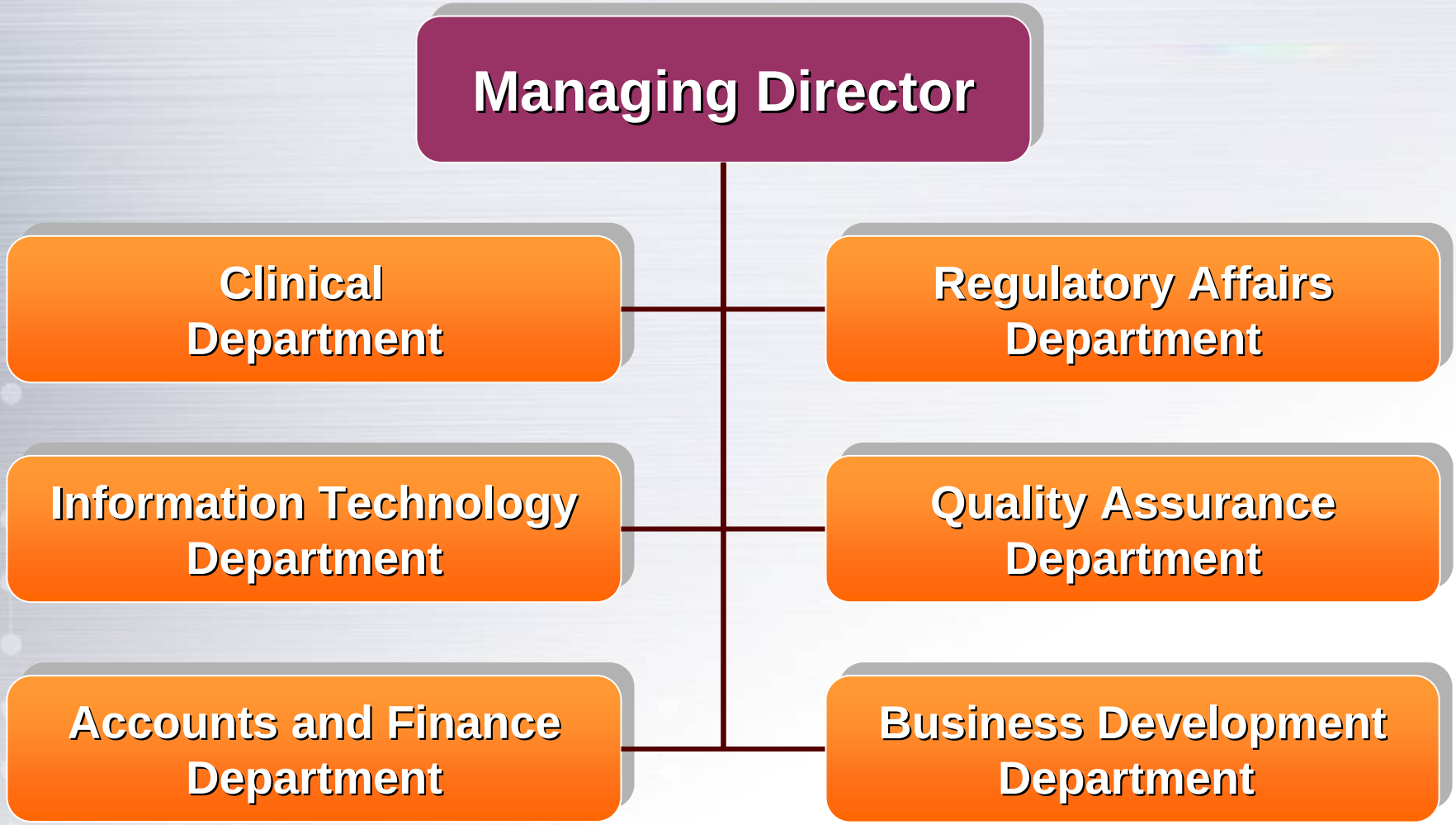
Who we are?

…established in December of 2004,
is a UK registered full service CRO

…was founded by the well-qualified specialists
in the different fields of medicine with vast
experience in conducting clinical trials

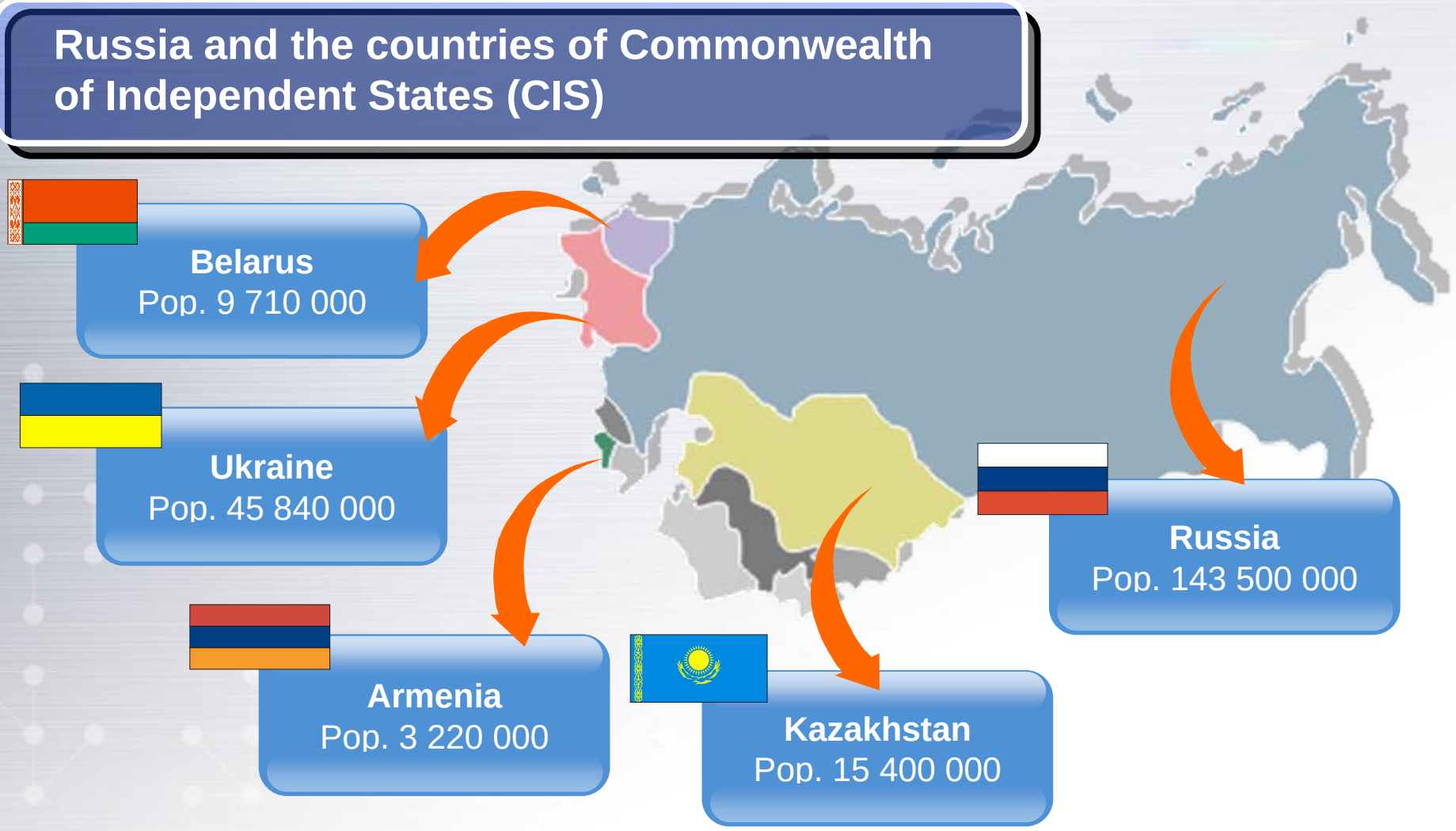
…specializing in conducting of clinical trials in Russia
and throughout Central and Eastern Europe

Organizational Chart



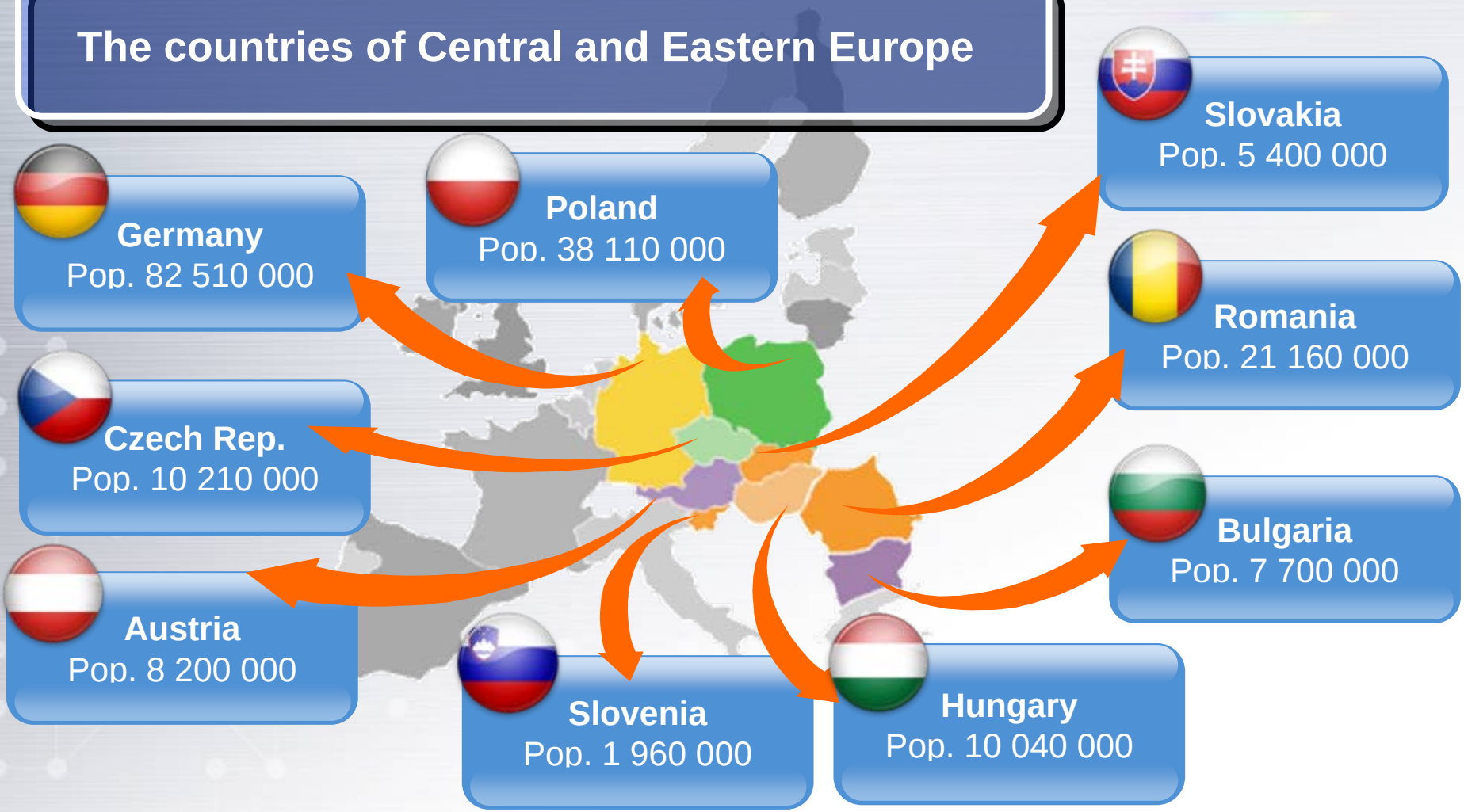
The territory where we operate

Russia and the countries of Commonwealth of Independent States (CIS)



The territory where we operate

The countries of Central and Eastern Europe



Our Services

Congenix offers an integrated package of customized services in I-IV phase clinical trials

- Regulatory Affairs (the countries of CIS and CEE)
- Investigators' selection and Sites' qualification
- Project Management and Clinical Monitoring
- Sites' Management and grand/contract administration
- Quality Assurance and Quality Control
- Safety Surveillance
- Clinical Writing
- Data Management and Biostatistics

Our Services

Regulatory Affairs

Russia

Ministry of Public Health and Social Development

Central and Local Ethics Committees

CIS

Local Regulatory Authorities

Central and Local Ethics Committees

Preparation and submission of regulatory package for obtaining the Clinical Trial Authorization

Obtaining import and export licenses

Preparation and submission of study related documents for ethical expertise

Interactions in the course of study

Regulatory Bodies (FDA, EMEA)

Preparation of the documents for submission to the regulatory bodies of the countries of EU and US

Custom House

Customs clearance of investigational product and study supplies

Our Services

Clinical Trial Authorization System in Russia

Ministry of Health
and
Social Development

→ Federal State Institution “Scientific Center of Medical Product Expertise”

→ Central (Federal) Ethics Committee

Our Services

Regulatory Affairs: Russia

List of documents to be submitted for the obtaining CTA

In English

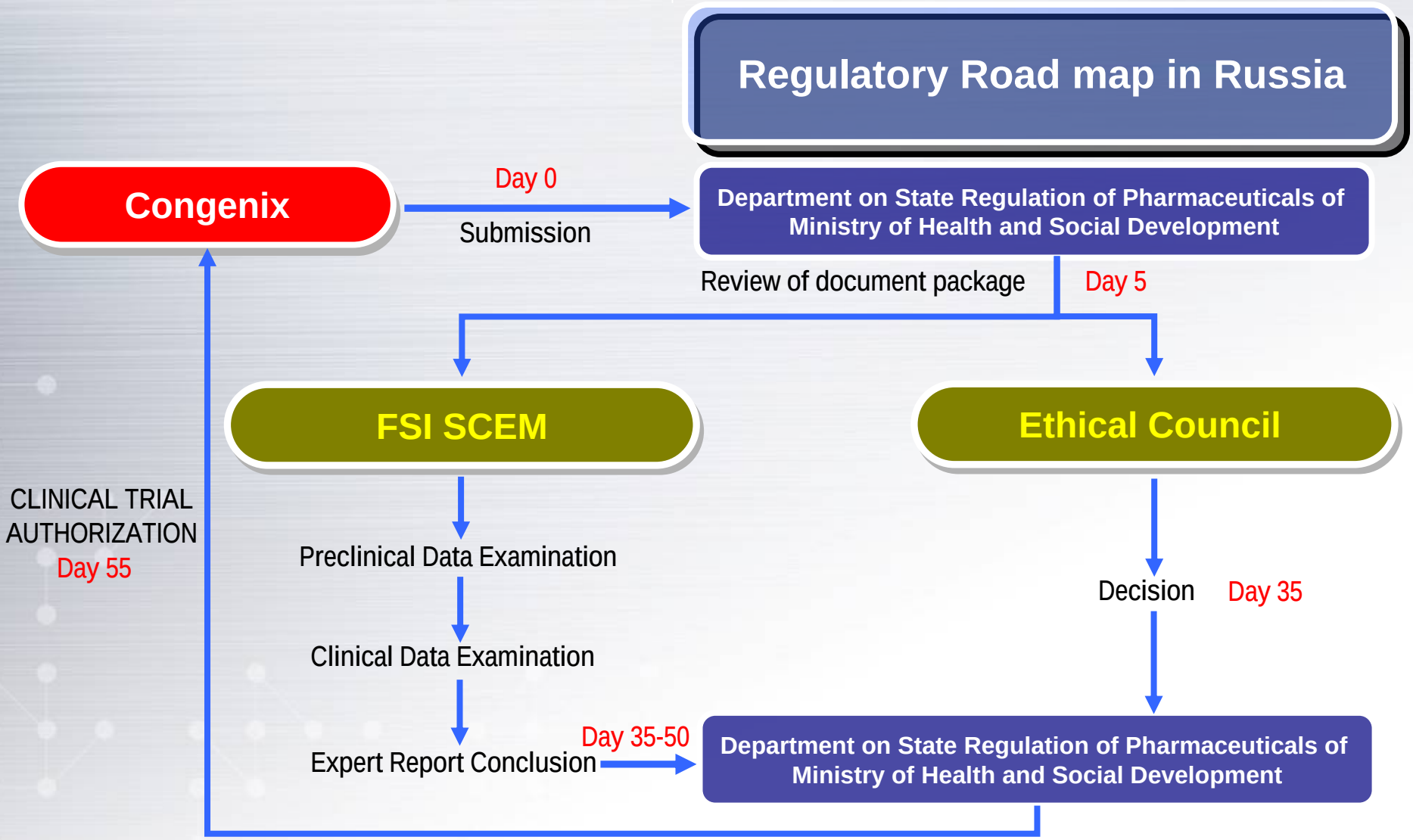
- Power of Attorney (Apostil)
- Clinical Trial Protocol
- Investigator Brochure (IB)
- Draft of CRF
- Patient's Information and Informed Consent
- Certificate of Analysis for IMP
- GMP Certificate

In national languages

- Submission letters to the local RAs and ECs
- Local study insurance
- Translation of Clinical Trial Protocol
- Condensed translation of IB
- Patient's Information and Informed Consent
- Draft of Hospital Agreement
- List of sites
- CV of Investigators

Our Services

Regulatory Affairs: Russia



Our Services

Regulatory Affairs: Russia

Regulatory Road map in Russia

Federal State Institution

Federal Ethics Committee

Favorable Decisions

Ministry of Health

Clinical Trial Authorization

Congenix

It usually takes about **60 working days** to get the Clinical Trial Authorization in Russia

Our Services

Clinical Trial Authorization System in Ukraine

Ministry of Health

State Pharmacological Center (PharmCenter)

Central Ethics Committee (in country)

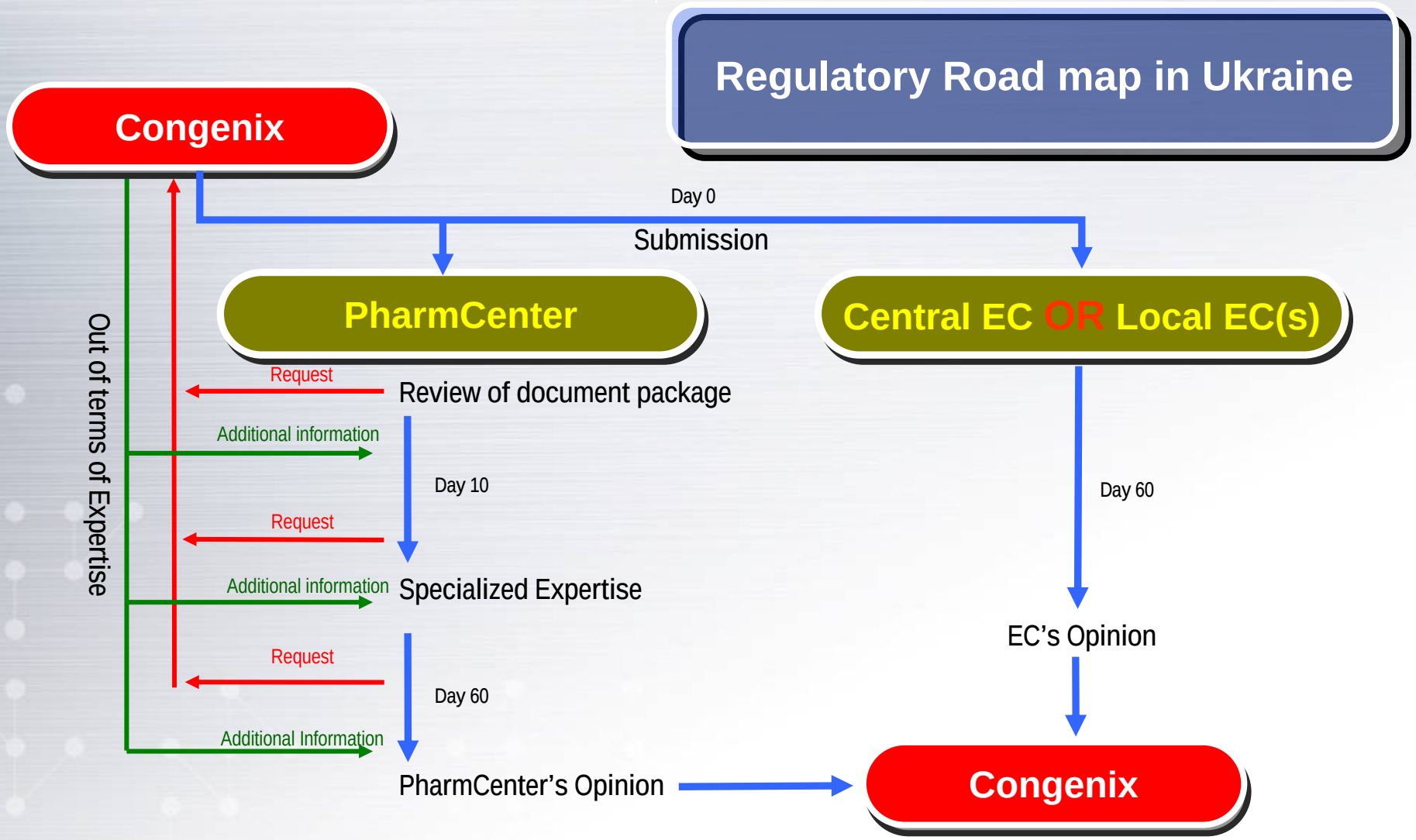
Local Ethics Committee (in site)

Local Ethics Committee (LEC) approves the trial ***only*** in appropriate site. CEC does not approve trial in this site in case of approval by LEC.

Central Ethics Committee (CEC) approves the trial in country. All local Ethics Committees accept its opinion.

Our Services

Regulatory Affairs: Ukraine



Our Services

Regulatory Road map in Ukraine

PharmCenter

Central EC or Local EC(s)

Favorable Decisions

Clinical Trial Authorization

It usually takes about 2,5 month to get the Clinical Trial Authorization in Ukraine

Our Services

Regulatory Affairs: Ukraine

List of documents to be submitted for the obtaining CTA

In English

- Power of Attorney (Apostil)
- Clinical Trial Protocol
- Investigator Brochure (IB)
- Master Label of IMP
- Patient's Information and Informed Consent
- Certificate of Analysis for IMP
- GMP Certificate

In national (or Russian) language

- Submission letters to the local RAs and ECs
- Clinical Trial Application (is equal to EU)
- Translation of Clinical Trial Protocol
- IMP Dossier
- Patient's Information and Informed Consent
- List of abroad CAs where study is reviewed
- CV of Investigators and List of sites
- Brief info about all trials currently conducting
- Local Study Insurance

Our Services

Clinical Trial Authorization System in Belarus

Ministry of Health

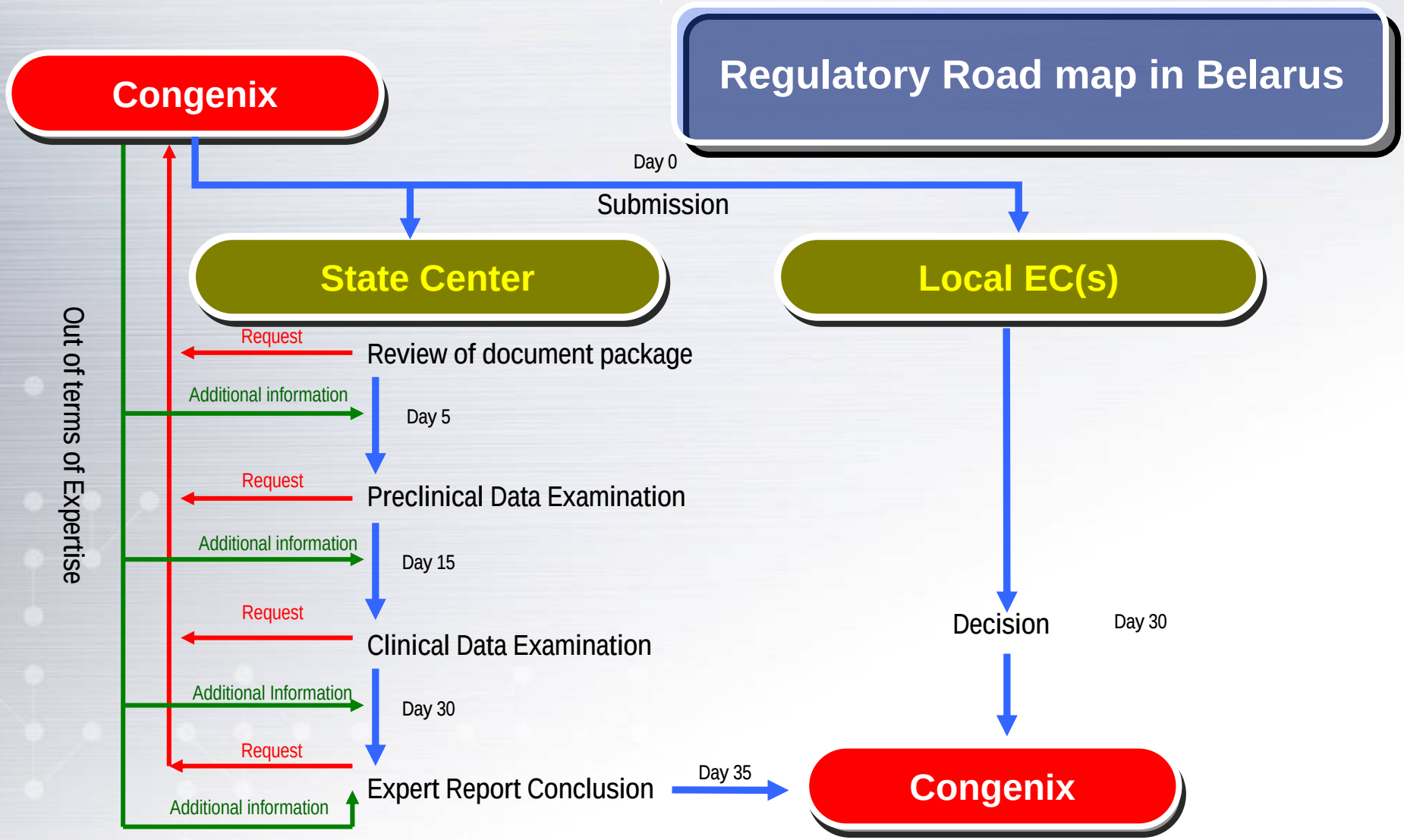
State Center of Expertise in Public Health

Local Ethics Committee (LEC) approves the trial ***only*** in appropriate site. There is no Central Ethics Committee in Belarus.

Local Ethics Committee(s)

Our Services

Regulatory Affairs: Belarus



Our Services

Regulatory Road map in Belarus

State Center

Local EC(s)

Favorable Decisions

Clinical Trial Authorization

It usually takes about 1,5 month to get the Clinical Trial Authorization in Belarus

Our Services

Regulatory Affairs: Belarus

List of documents to be submitted for the obtaining CTA

In English

- Power of Attorney (Apostil)
- Clinical Trial Protocol
- Investigator Brochure (IB)
- Draft of CRF
- Patient's Information and Informed Consent
- Certificate of Analysis for IMP
- GMP Certificate

In national (or Russian) language

- Submission letters to the local RAs and ECs
- Local study insurance
- Translation of Clinical Trial Protocol
- Condensed translation of IB
- Patient's Information and Informed Consent
- Draft of Hospital Agreement
- List of sites
- CV of Investigators

Our Services

Project Management

Project's Set-Up

- Project resource planning
- Feasibility assessment
- Budget estimates
- Site selection
- Developing a monitoring guidelines
- Initial training for the project team
- Contracting with study centers, Investigators and 3rd parties
- Investigator's meeting
- Co-ordination of study supplies custom clearance and shipment

Project's Course

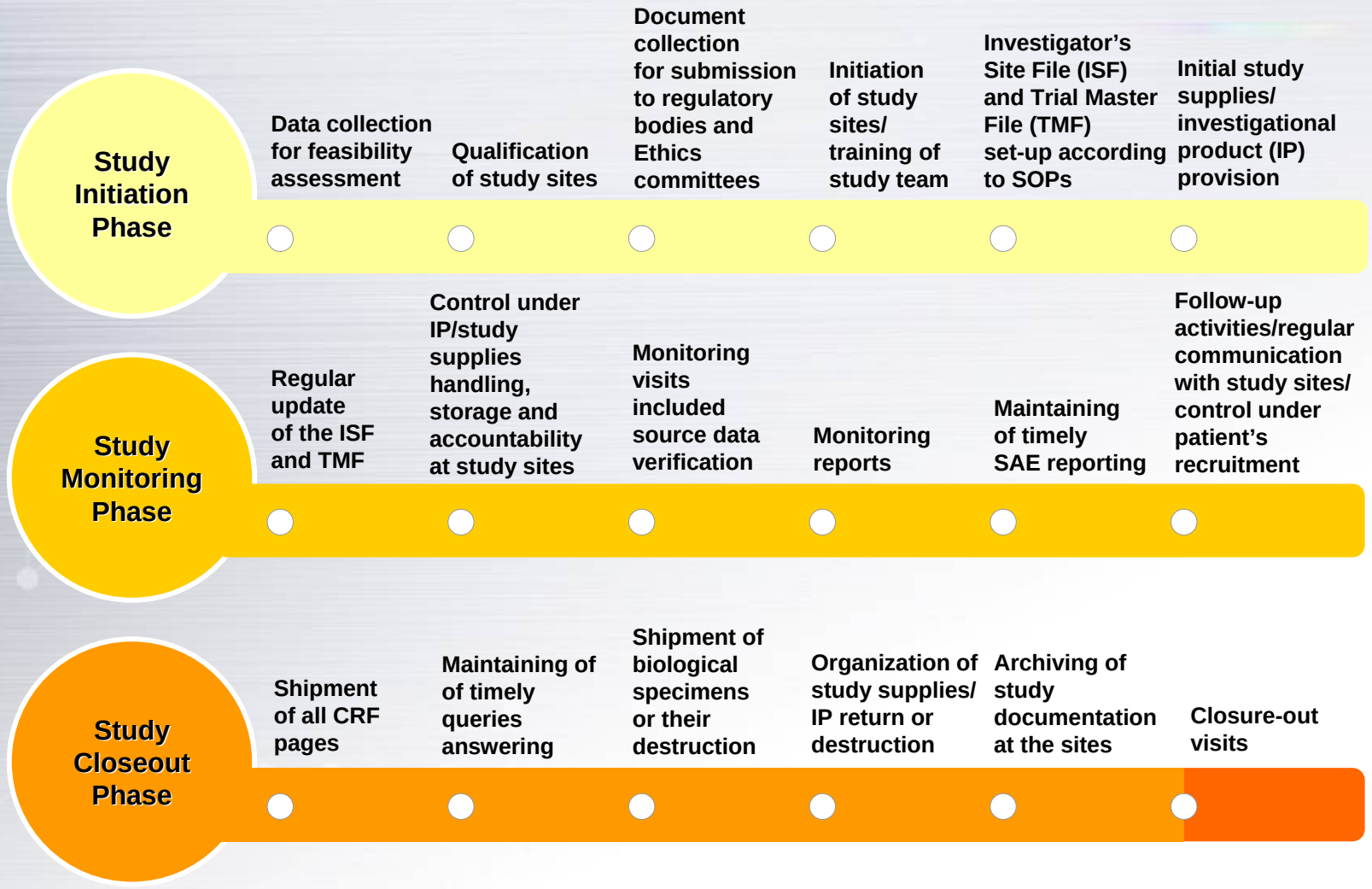
- Control of compliance with the client's requirements
- Effective management of the budget
- Co-monitoring visits
- Ongoing communication with client
- Progress meetings in the course of the study
- Regular study status reporting
- Grant negotiation and administration

Project's Closure

- Reconciliation between the project team and the data management group
- Co-ordination of study supplies return and/or destruction
- Final project team meeting
- Co-ordination site closure visits
- Archiving study materials

Our Services

Clinical Monitoring

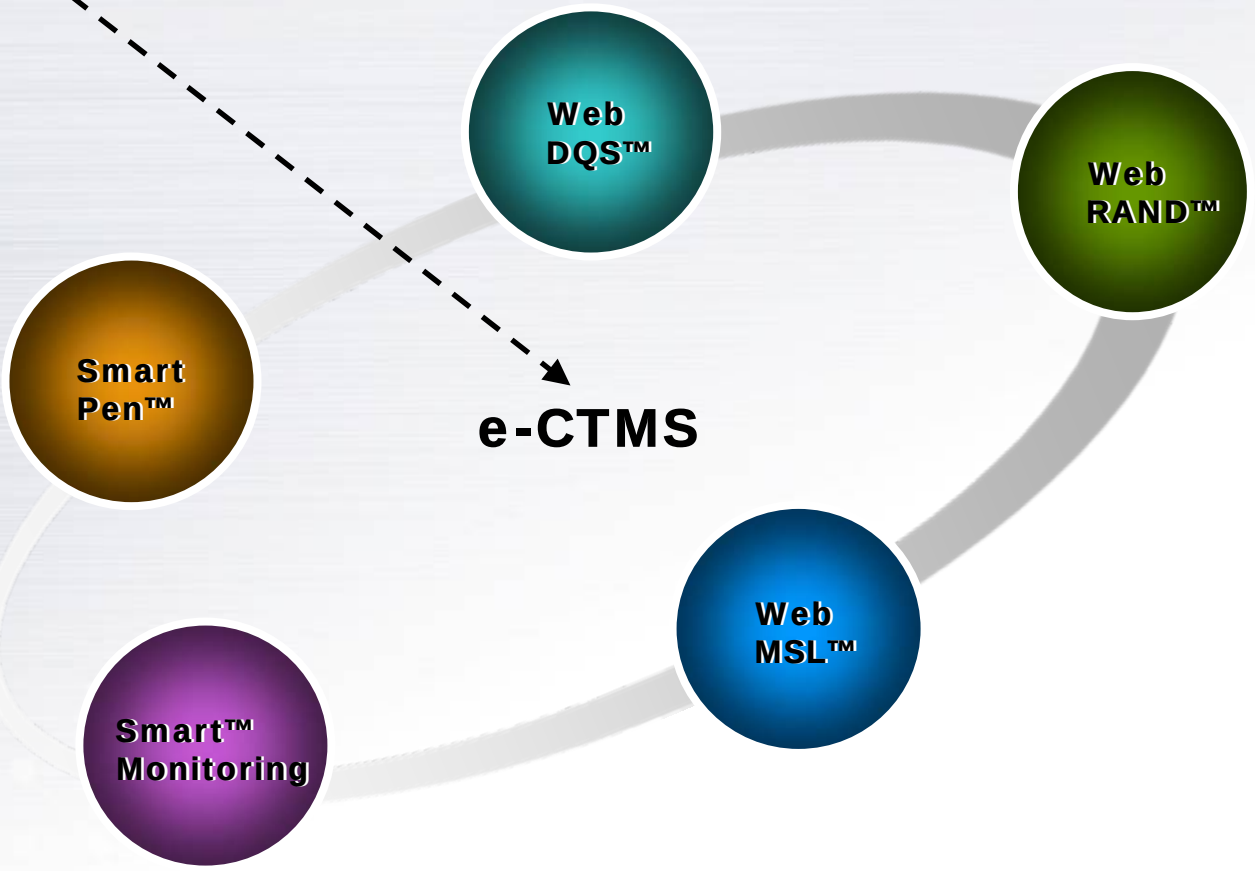


Our Services

Adaptive Clinical Trials

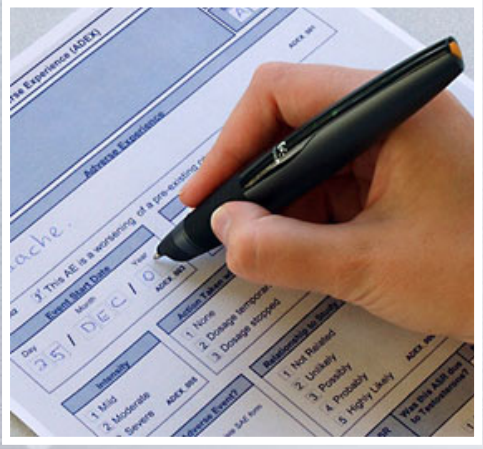
Congenix

Congenix is connected to e-Clinical Trial Management System which is the core element of adaptive methodology developed and implemented by Health Decisions™ (www.healthdec.com)



Our Services

Data Management



Data Management

Congenix uses high-performance e-CTMS developed by Health Decisions™, emphasizes rapid data collection, processing and analysis, and makes validated real-time data available continuously through secure project websites.

We use unique **SmartPen™** technology which includes the following advantages:

✓ Goes beyond web-based EDC to provide continuous collection of performance metrics as well as data;
✓ Gives managers and sponsors continuous, real-time information, permitting tighter management and more informed decision-making;
✓ Intuitive data entry and reduced clerical workload at sites;
✓ Reduced query rates because of rapid feedback;
✓ Faster clean data for DSMB, adaptive studies, and management;
✓ Can be used for PROs and combined other data capture methods in the same study;
✓ 21 CFR part 11-compliant, extensive study and geographic experience;
✓ Saves time and reduces costs over both traditional paper- and web-based EDC systems.

Our Services

Biostatistics

Planning

- ✓ Study protocol design;
- ✓ Definition of study endpoints;
- ✓ Sample size determinations;
- ✓ Statistical methodology specifications;
- ✓ Randomization plans;
- ✓ Contents of the CRF;
- ✓ Specifications for data validation;
- ✓ Plans for comprehensive statistical analysis;
- ✓ Shells and/or specifications for all planned tables, figures, and lists.

Analysis

- ✓ Development of analysis databases;
- ✓ Pharmacokinetic modeling and analyses;
- ✓ Inferential analyses;
- ✓ Exploratory analyses;
- ✓ Interim analyses;
- ✓ Integrated summaries of safety/efficacy;
- ✓ Data validation.

* All analysis are performed using the SASR by biometricians and SAS programmers with broad therapeutic experience and regulatory experience.

Reporting

Biometricians assist in the production of high-quality clinical study reports through the development of clear and concise documentation of statistical methods, including planned and exploratory analyses and accurate interpretation of results. Biometrics department also collaborates on ISS and ISE reports and provides support for electronic submissions in adherence to applicable regulatory guidances.

Our Services

Quality Assurance and Quality Control

Standard **O**perating **P**rocedure**s** cover all Congenix's activities and developed together with ***Quality and Compliance Consulting, Inc*** (USA) and ***Verdandi AG*** (Switzerland)

Congenix establishes an annual **Audit Program** to verify conformance to contractual requirements, sponsor needs, contractual obligations and regulations, to obtain and maintain confidence in its capability to deliver quality services and to improve existing processes.

According to ICH GCP, all personnel involved in clinical trials must be qualified by education, training and experience to perform their respective task(s). For this reason Congenix's training program devoted to the fundamental principles of clinical trials (**Induction trainings**) or provide the latest information on clinical trials (**Advanced trainings**).

Our Experience

Congenix has the combined experience in the different therapeutic areas

- Cardiology
- Endocrinology
- Gastrointestinal diseases
- Psychiatry
- Dermatology
- Oncology
- Immunology and Allergology
- Kidney diseases
- Ophthalmology
- Pediatrics

Our Locations

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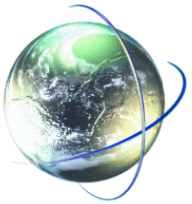
Contact Us



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Thank You!