Corporate Presentation

2018

Company Overview

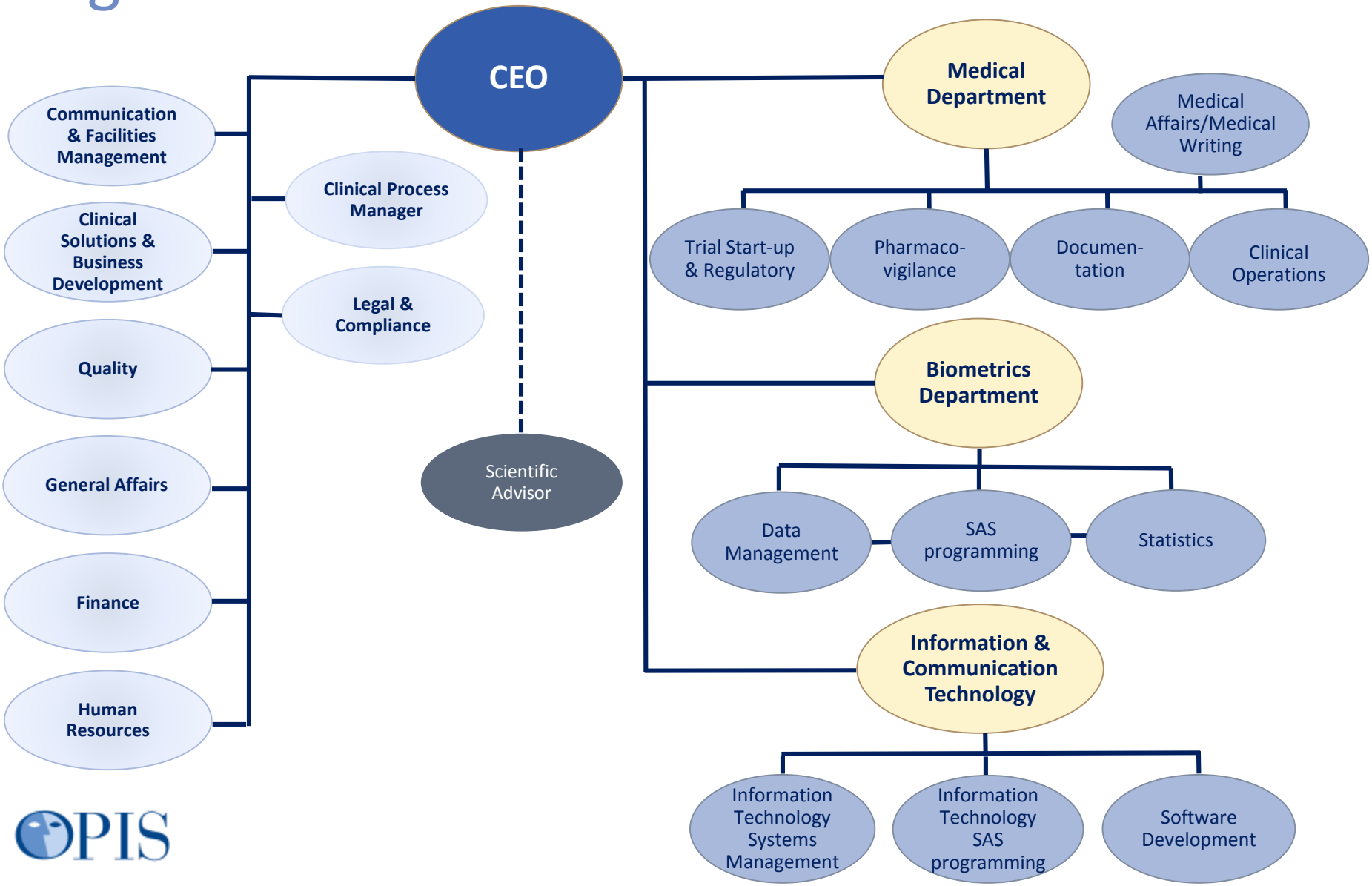
OPIS is an international CRO providing:

- A wide range of clinical and e-clinical services for Pharmaceutical and Biotechnology Industries, Medical Device companies as well as Academic Institutions and Non-Profit organizations
- International and Local Phase I-IV studies
- Observational studies and IITs

OPIS

20 Years

Organisation



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Locations and International Structure

Trial Leader coordinates international activities

OPIS Services at a glance

- Medical Writing and Scientific Advice
- Regulatory and Clinical Operations
  - Site selection
  - Trial Start-up
  - Project Management
  - Monitoring
- Quality Management
- Study Data
  - Document management
  - Data management
  - Statistics
  - E-clinical suite (EDC platform)
- Pharmacovigilance
- Project Control
- Training

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Medical Writing

A qualified team of medical writing experts and medical doctors produce and edit:

Full range of regulatory and **clinical documentation**	Across all therapeutic areas and across all clinical research phases	In short timeframes	Stand-alone or part of full service

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Regulatory and Clinical Operations

Regulatory and Start-up

- Preliminary site assessment (Investigators database in various indications)
- Feasibility checks
- Site Selection
- Adaptation of documents to local requirements
- Contract negotiations
- Regulatory and EC submissions

Project Management

- Staff Training & Management
- Coordination and Supervision of Monitoring Activities
- Planning & Tracking patient recruitment
- Ensuring proper management of all study related data
- Ensuring streamlined communication among parties
- Project execution in compliance with all applicable requirements
- Acting as SPoC for Sponsors

Monitoring

- Site visits according to Monitoring Plan
- Remote monitoring, if required
- Site support between visits
- Issue management and escalation, if applicable

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Quality Management

- Check of documentation for submission (Trial Start-Up)
- Check of study documentation (Trial Master File)
- Random check of monitoring reports; alternatively complete check of monitoring reports of the center under evaluation (e.g. in preparation of audits)
- Co-monitoring (tutoring and site compliance visits)
- Site audit/inspection preparation
- Training sessions
- Further quality services (e.g. centralized management and distribution of SOPs) or checks upon request (e.g. specific documentation such as training docs, financial disclosure forms, CVs)

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Study Data Handling

Integral - high quality - reliable - analyzable DATA

Biometry

- Data Management
- Biostatistics
- SAS Programmers

Clinical.net

- In-house developed
- > 10 years experience
- Extendible & customizable

CRF design

ICH/GCP guidelines	*Protocol specifications*	*CDISC standards*

Validated EDC

eCRF implemetation	*FDA 21 CFR Part 11 compliant*	*Modular, web-based technology*

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Clinical.net Study Portal

Clinical.net
POWERED BY OPIS

Study Web Portal

- Electronic Data Capture
- On line Randomisation
- E-learning
- Protocol Deviation Tool
- Import from External Sources
- Drug Management
- eSAE

GCP and FDA 21 CFR Part 11 compliant

Fully customizable and configurable

www.clinical.net

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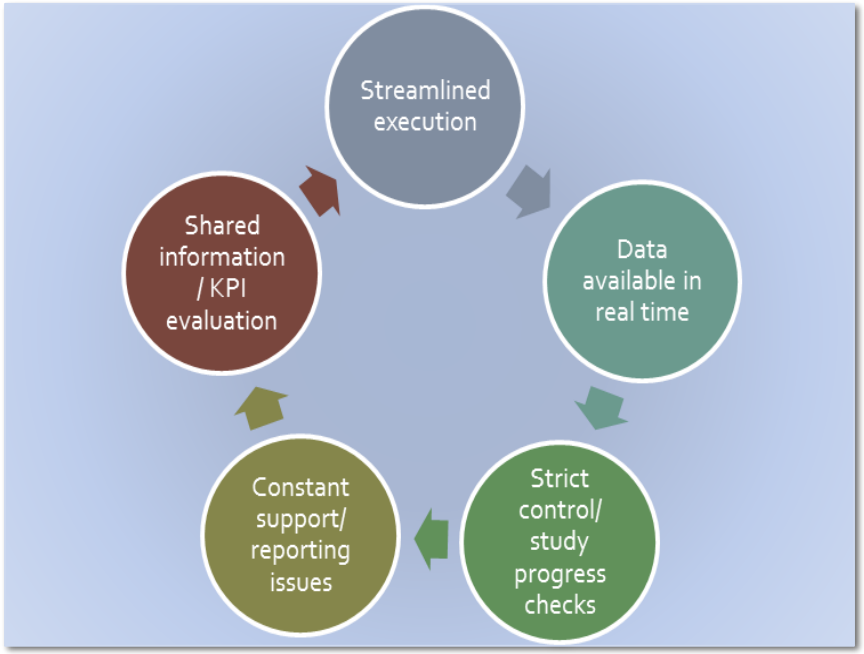
Pharmacovigilance

Flexible suite of pharmacovigilance and safety monitoring as stand-alone or part of full service package

Project Control

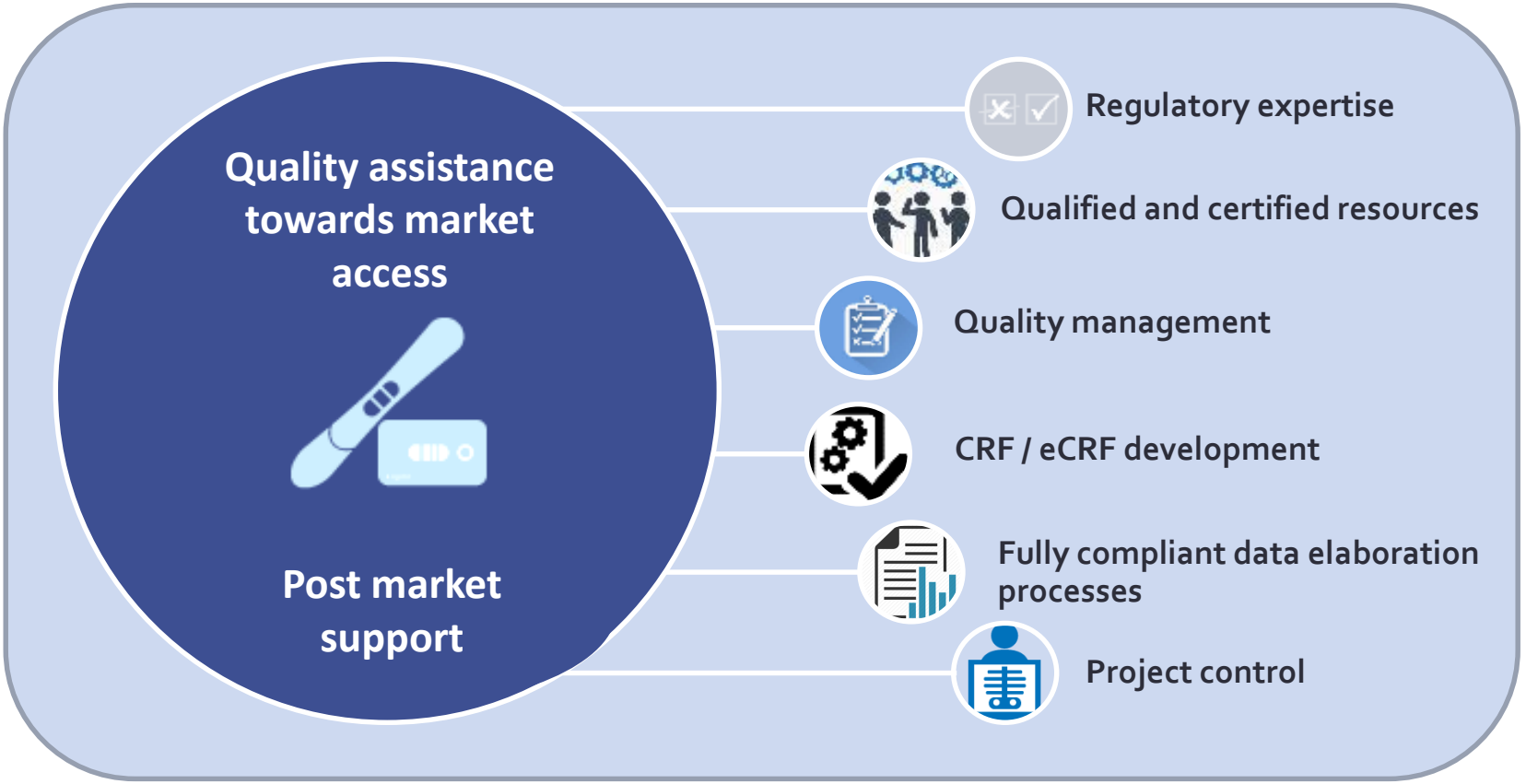
All activities strictly monitored



Objectives

- Ensure that contractual timelines and requirements are met
- Provide extrapolation and data query tools for reporting to the Sponsor, e.g. supplying exports, reports, periodic status updates, as required
- Identify potential interfaces with Sponsor's systems
- Facilitate information sharing

Clinical Investigations for Medical Devices



UNI EN ISO 14155-2012 compliant trials

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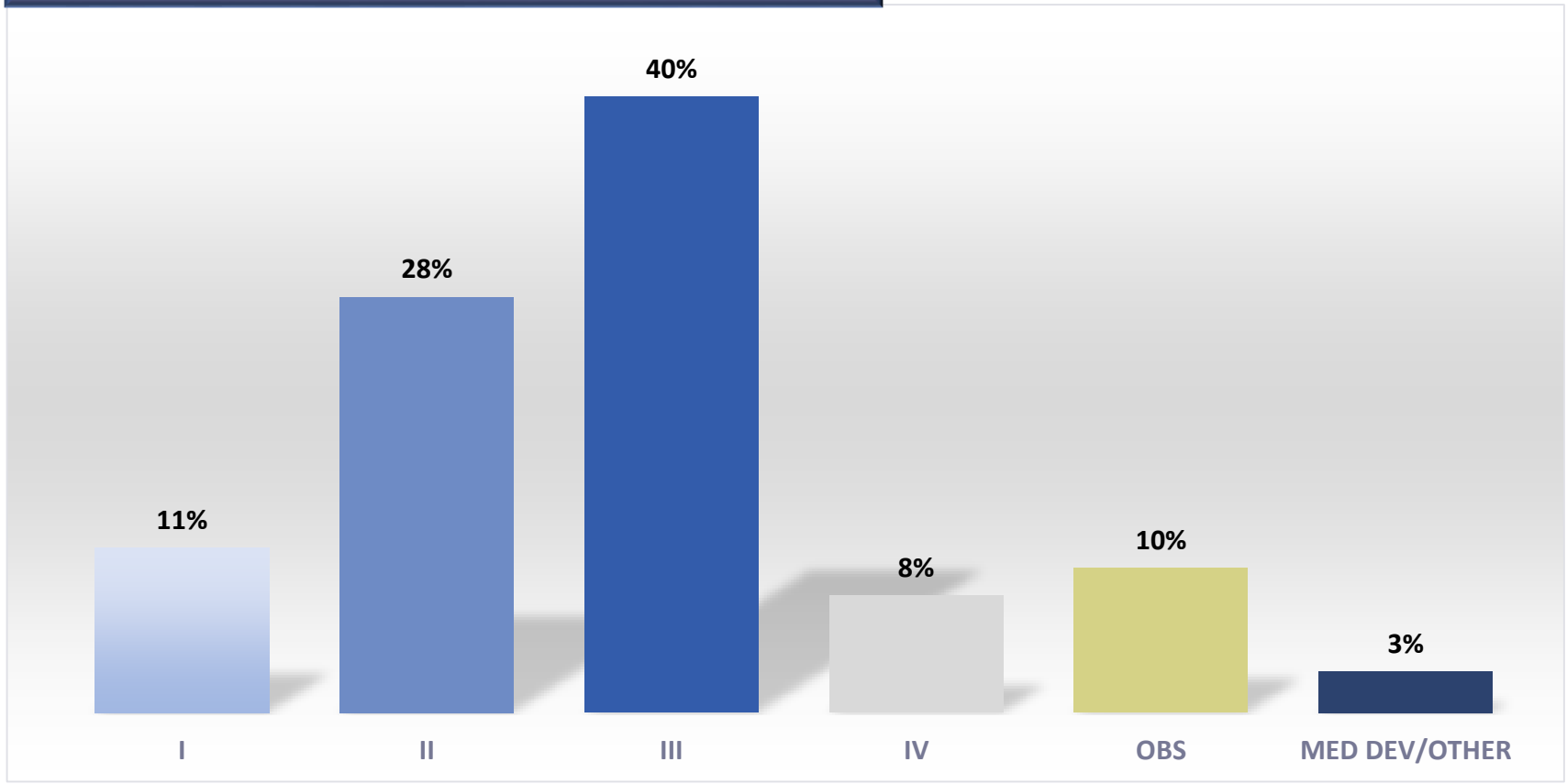
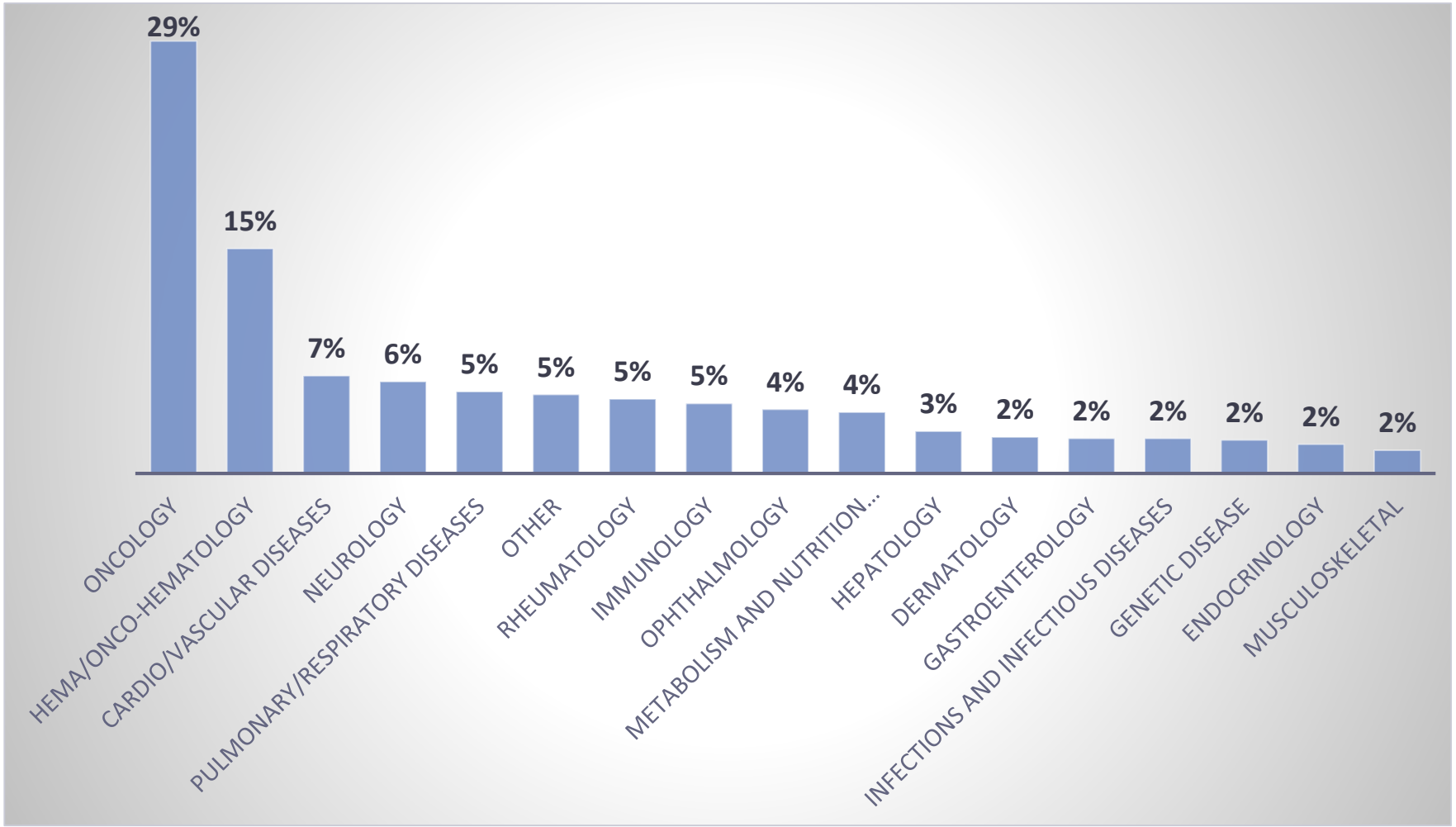
Trial Distribution/phase

Experience based on more than 1000 trials

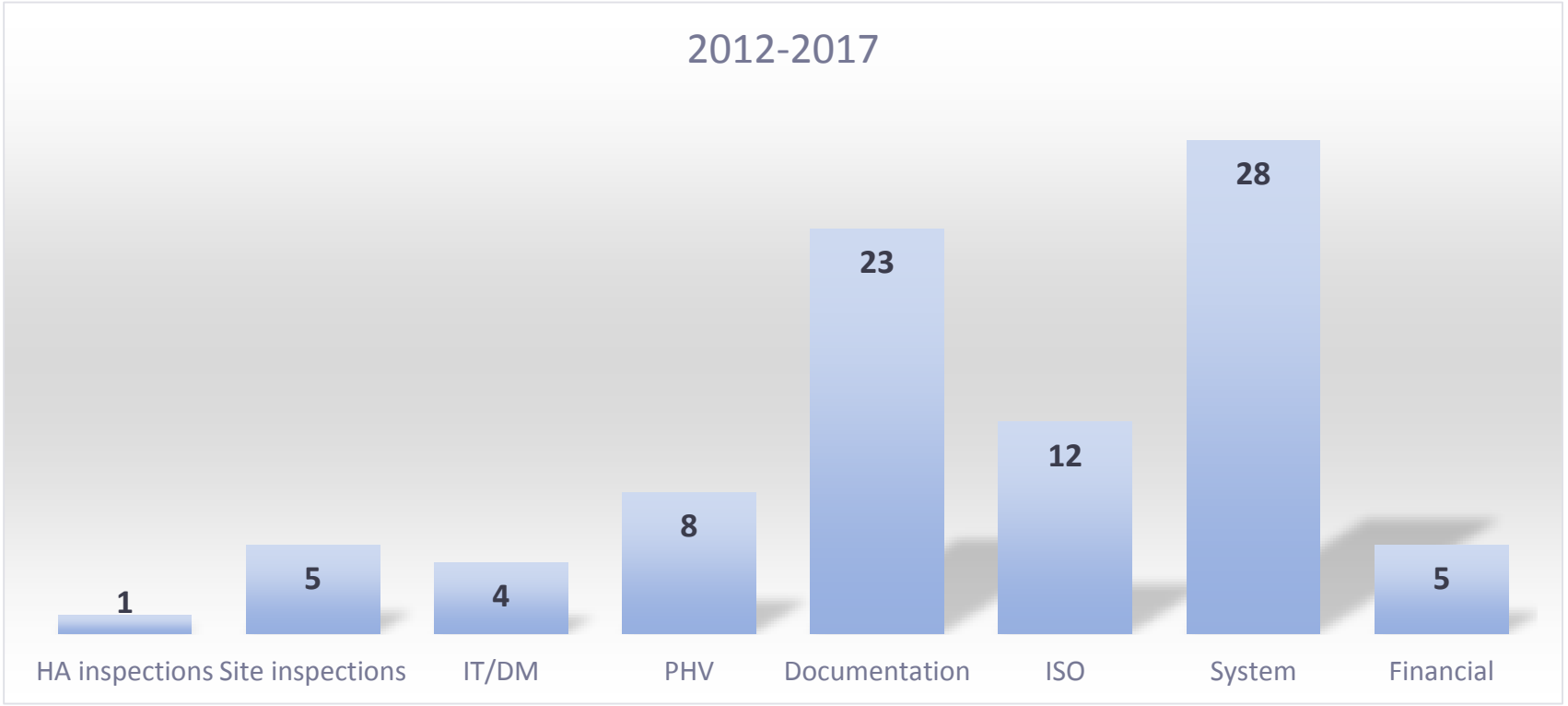


Therapeutic Areas



OTHER:
Psychiatry/Psychology, Vaccines, Urology, Gynecology, Healthy Volunteers, Nephrology, Dental and Oral Health, Endocrinology, Diagnostics

Audits and Inspections



In addition 136 Site Audits were performed in the last 5 years

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Best practice

We believe in

People
- Trust
- Transparency
- Professionality
- Reliability

Collaboration
- Partnerships
- Teams

Innovation
- Technology
- Development
- Growth

Efficient work
- Timelines
- SPoC
- Streamlined processes

OPIS invests in training

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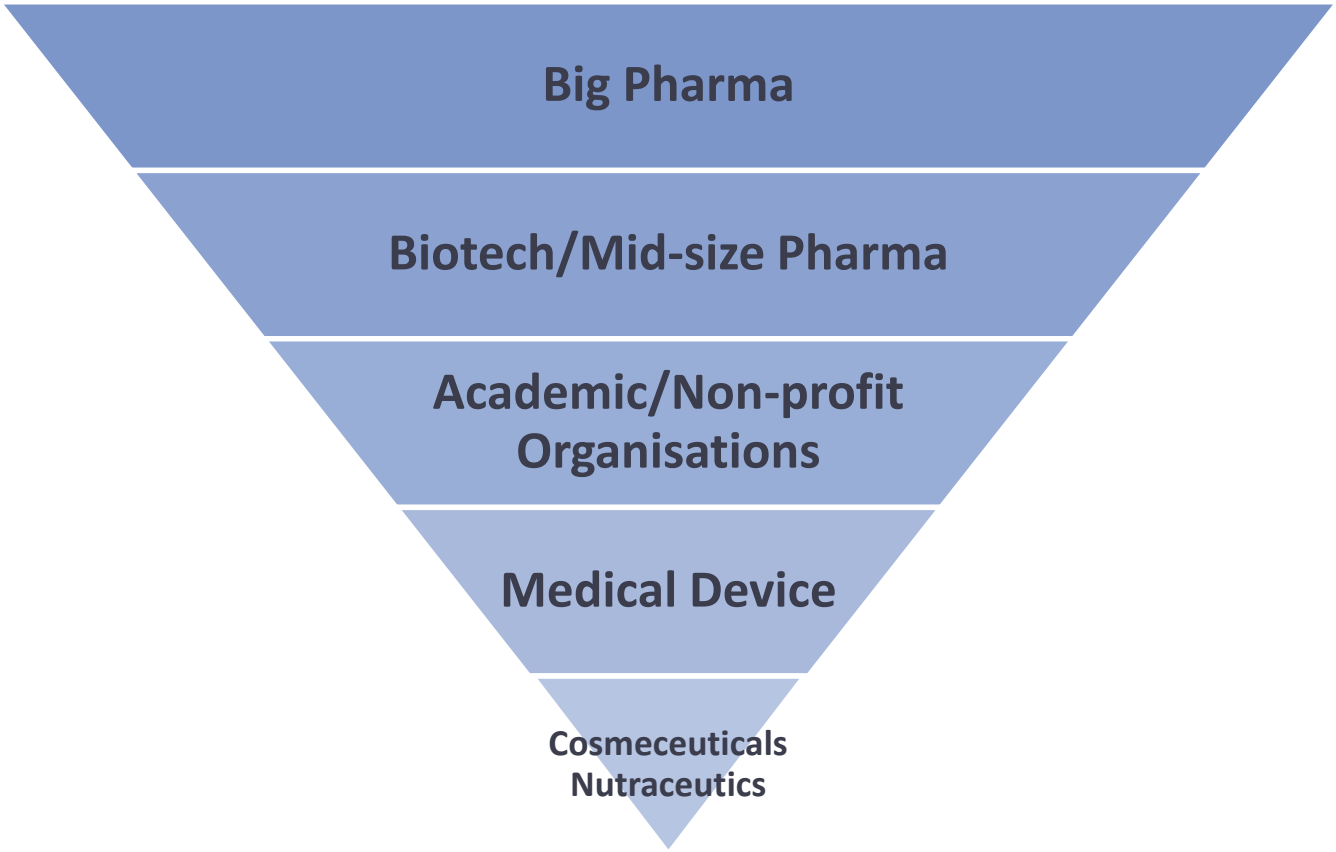
Sponsor Collaborations



20 years make a world of difference
if you're true to yourself.

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