PHARMASSIST
CONTRACT RESEARCH ORGANIZATION

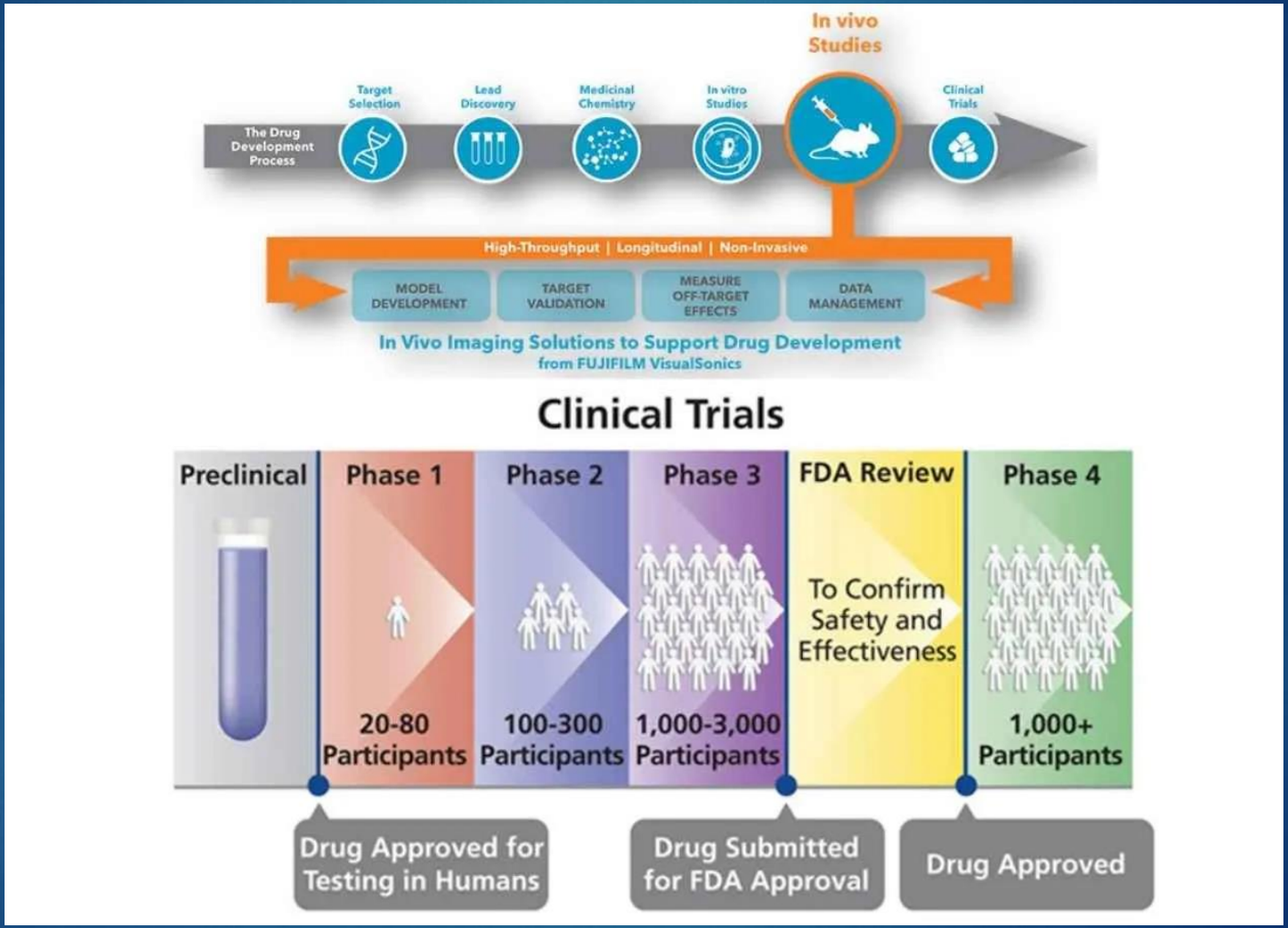
Ο Χημικός στη Βιομηχανία

ΙΩΑΝΝΑ Ι. ΚΟΥΚΛΗ, PHD
FOUNDER & MANAGING DIRECTOR PHARMASSIST LTD

Contract Research Organization (CRO)

Ένα Contract Research Organisation (CRO) είναι ένας οργανισμός που παρέχει υποστήριξη στις βιομηχανίες φαρμάκων, βιοτεχνολογίας και ιατροτεχνολογικών προϊόντων, με τη μορφή υπηρεσιών που ανατίθενται σε εξωτερικούς συνεργάτες με σύμβαση. Οι κύριες υπηρεσίες που αναλαμβάνει ένα CRO αφορούν στη διεξαγωγή κλινικών μελετών, την έγκριση & διαχείριση του κύκλου ζωής των φαρμακευτικών, βιοτεχνολογικών και ιατροτεχνολογικών προϊόντων, και τη φαρμακοεπαγρύπνηση.

AN OVERVIEW OF NEW DRUG DISCOVERY AND DEVELOPMENT



Pharmassist Ltd CRO

Pharmassist Ltd is a full-service Contract Research Organisation located in Athens, Greece, London, United Kingdom and Nicosia, Cyprus. It operates in Europe since 1999 providing services in:

- Clinical Trials
- Medical Affairs
- Pharmacovigilance
- Regulatory Affairs
- Quality Management

- Clinical Operations
- Advice on Clinical Development
- Pharmacovigilance
- Regulatory Strategy
- Compilation of complete registration dossiers
- Registration & Life-Cycle management of marketing authorisations
- Pricing & Market Access Strategy
- Development of SOPs in accordance to GVPs, GCPs, GMPs, GDPs
- Writing and/or reviewing of Quality, Technical & Vigilance Agreements

CLINICAL OPERATIONS

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- Feasibility studies, planning, resourcing and logistics
- Trial files compilation
- Regulatory and IRB submissions
- Site preparation and trial initiation
- Training of investigators on GCPs
- On-site study coordination
- Study monitoring
- Site close-out
- Project Management

MEDICAL AFFAIRS
Medical Writing

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- Clinical Studies (study documents – Protocol, ICF, CRF, IB, patients' materials, CSR)
- Regulatory (clinical and non clinical overviews, clinical evaluation reports, biological assessment reports)
- Pharmacovigilance (contribution to Risk Management Plans, Periodic Safety Update Reports, Expert Statements)
- Market Access (Clinical Effectiveness part of the dossier)

MEDICAL AFFAIRS
Medical Writing

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- IMPD Drafting (CMC, PD, PK, toxicology clinical protocols) including full scientific & regulatory support therefor (e.g. Specification setting, stability, potency assay development etc.)
- Experience in small molecules, antibodies, therapeutic proteins, Advanced Cell & Gene therapies (oncolytic viruses, Stem cells), herbal drug preparations
- Preparation of Briefing documents for Scientific Advice from EMA and EU Regulatory Authorities, FDA, India – Prosecution & support

MEDICAL AFFAIRS
Medical Support/Expertise

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- Clinical Studies (feasibility studies, training on therapeutic area and protocol, medical monitoring)
- Regulatory (medical translations, medical review of product's regulatory documents – SPC, PIL)
- Pharmacovigilance (Medical review of ISCRs, aggregate reports)
- External customers (Promotional material review, trainings, medical information, product defense, organization of advisory boards, early access programs)

Through a qualified team of 12 Medical/Scientific experts.

MEDICAL AFFAIRS

Medical Devices & In vitro diagnostics (IVDs) Services

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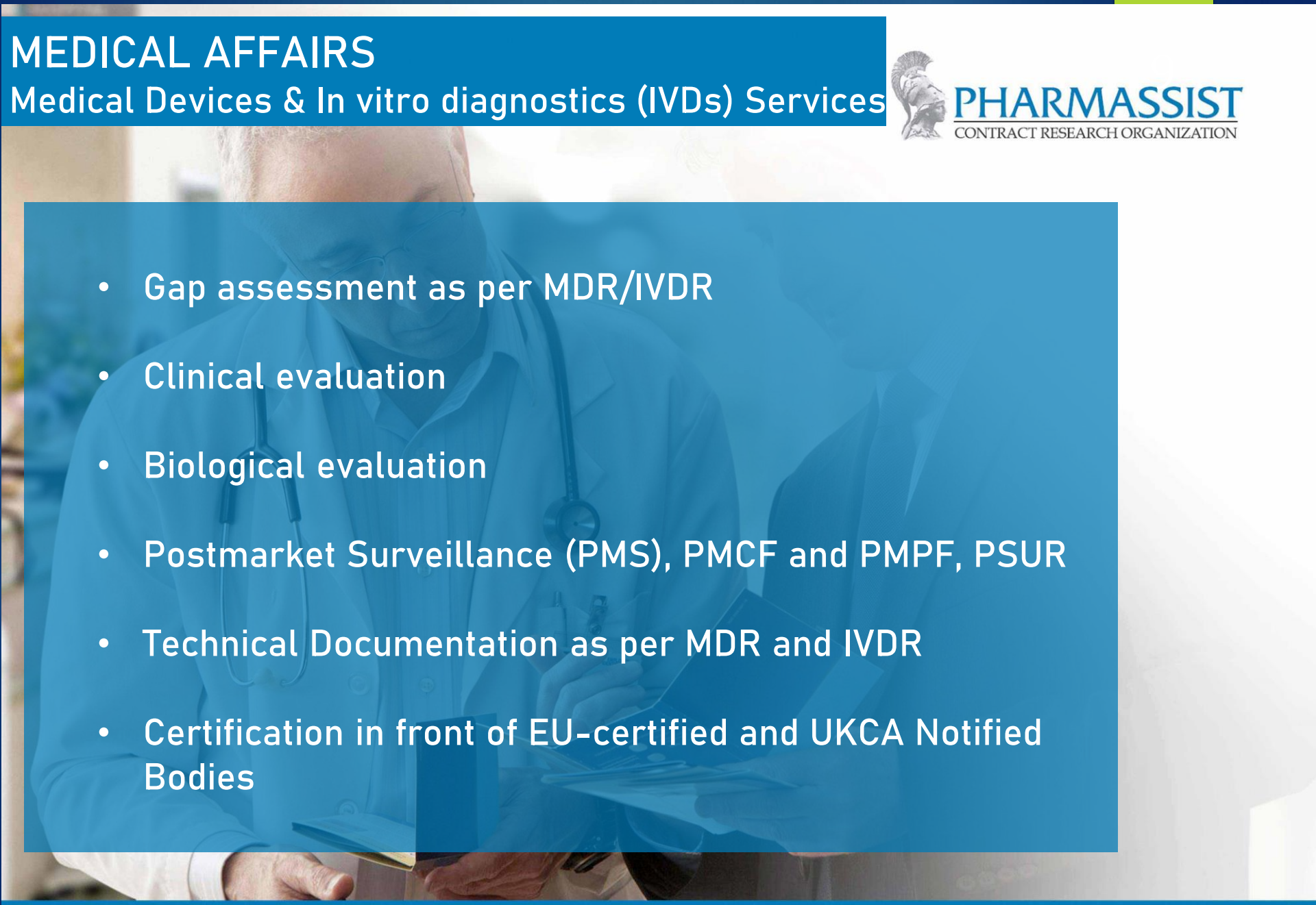

- Gap assessment as per MDR/IVDR
- Clinical evaluation
- Biological evaluation
- Postmarket Surveillance (PMS), PMCF and PMPF, PSUR
- Technical Documentation as per MDR and IVDR
- Certification in front of EU-certified and UKCA Notified Bodies

PHARMACOVIGILANCE
Postmarketing

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- Provision of EU QPPV and Deputy and development of PSMF
- Provision of local QPPVs
- Management of ADRs/AEs and other relevant safety information
- Preparation and submission of Aggregate Safety Reports (PSURs, PBRERs, ACOs)
- Monitoring of Product Safety (Signal Detection, Risk Benefit Assessment)
- Preparation of RMPs and Material for Risk Minimisation Activities

PHARMACOVIGILANCE
Postmarketing

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- Setting up (writing and/or review) of Standard Operating Procedures
- Pharmacovigilance Audits/ Inspections participation
- Local and Global scientific literature review
- Writing and/or reviewing of Safety Agreements
- Storage and protection of PV records
- Safety training/Inspection Readiness Training
- PV Audits Conduct, to contractual partners

VIGILANCE for non-medicinal products

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- Cosmetovigilance
- Responsible person & Post Marketing surveillance
- Reporting of SUEs and Safety Assessment
- Medical Device Vigilance
- Set up of MDV System
- Collection, investigation, assessment and reporting of medical device incidents
- Preparation of Periodic Summary reporting, Field Safety Corrective Action and Field Safety Notice

PHARMACOVIGILANCE IN CLINICAL TRIALS

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- Review of safety sections of study protocol
- Development of Safety Management Plan
- EudraVigilance registration
- SAE/ADR processing and expedited reporting (SUSARs reporting) to Competent Authorities (Eudravigilance, Ethics Committee) and Investigators
- Preparation and submission of Safety Reports and line listings

PHARMACOVIGILANCE IN CLINICAL TRIALS

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- Pharmacovigilance training to CRAs and Investigators
- Writing and/or reviewing of Safety Agreements
- Reconciliation of PV database with the Clinical Database
- Development of Dear Investigator Letter

REGULATORY AFFAIRS

Registration & Life-Cycle Management of Pharma Products

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Collection of technical data and scientific writing of chemical and pharmaceutical documentation

Preparation of registration dossiers in CTD, NeeS and eCTD format for National, MR and DC Procedures

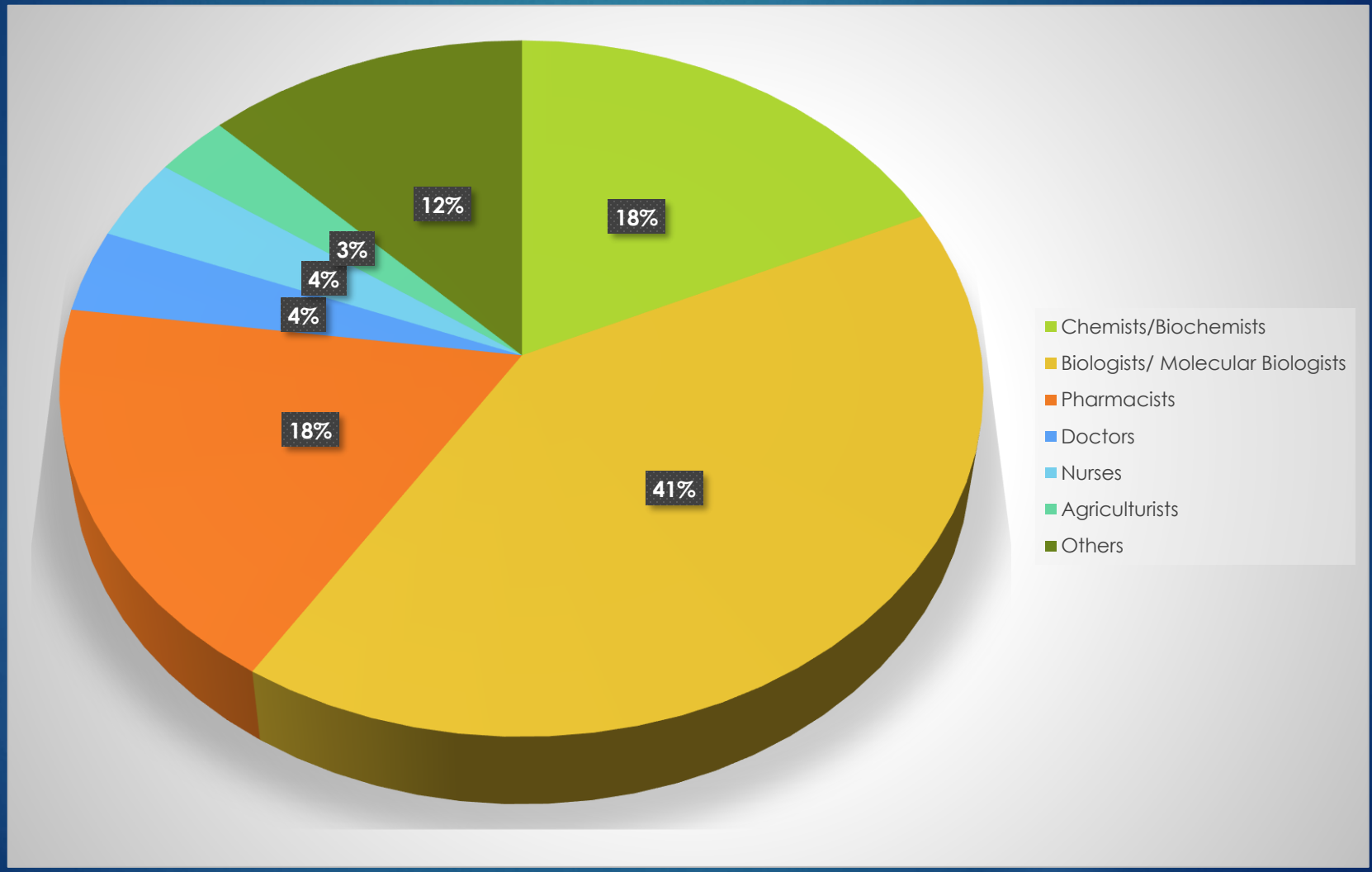
Coordination and execution of all activities pertaining to the registration and life-cycle management of marketing authorisations of medicinal products

Provisions of accurate translations of scientific documents (SPCs , PILs, training material)

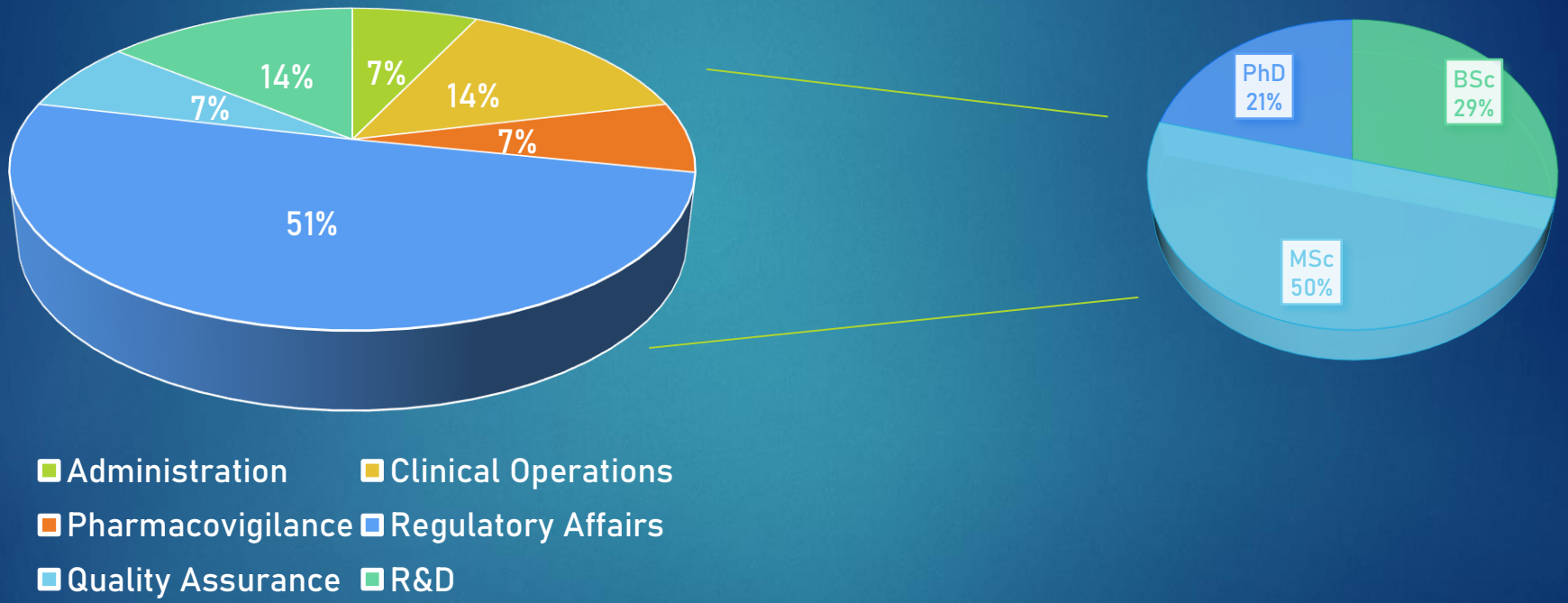
Employment opportunities

- Regulatory Affairs & Operations
- Clinical Research
- Scientific Writing
- Quality Assurance

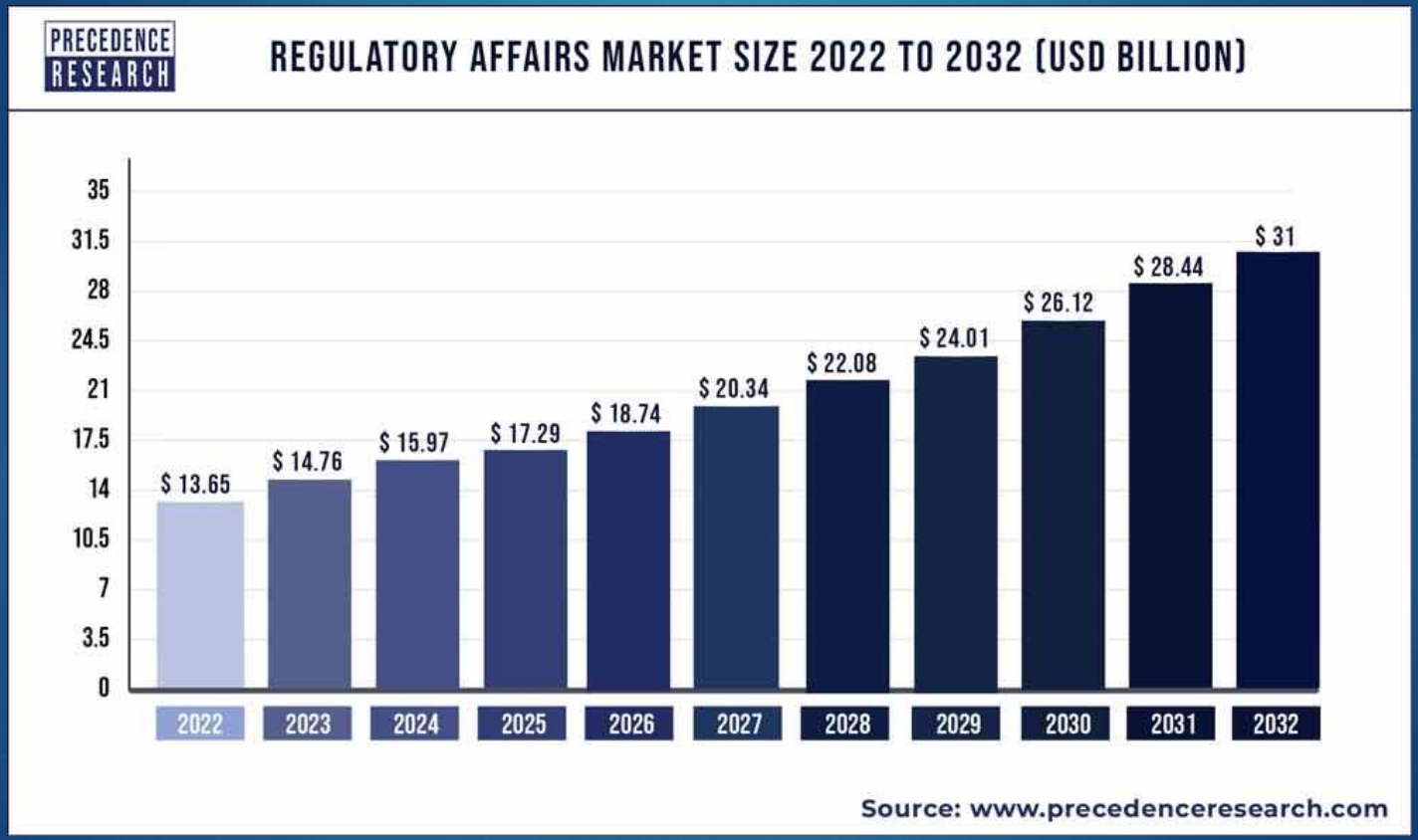
Staff of Pharmassist Ltd



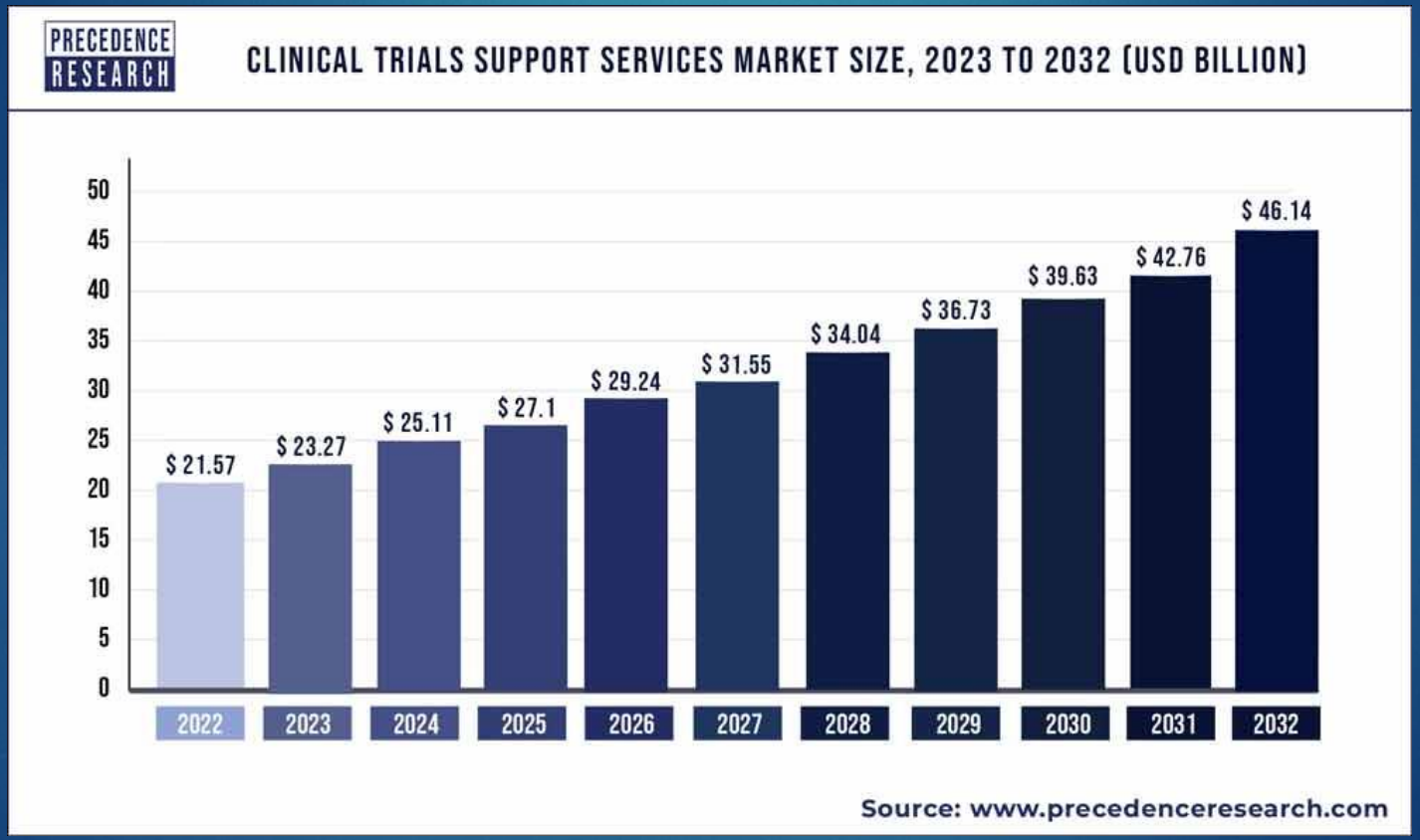
Chemists in Pharmassist Ltd

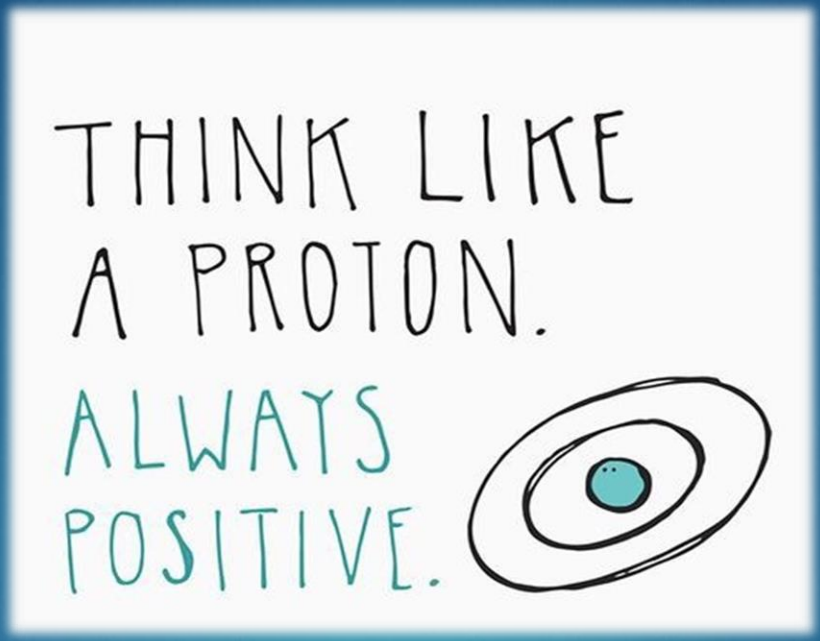


Regulatory Affairs Market (Regulatory Consulting, Legal Representation, Regulatory Writing & Publishing, Product Registration & Clinical Trial Applications)



Clinical Trials Support Services Market (Clinical Trial Site Management, Data Management, Patient Recruitment Management, Administrative Staff, IRB, Others)





Thank You !