



Serge Locquet
+(32)497 05.92.89
serge.locquet@keyrus.be



Nadia Bianco
+(32)(0) 2 627 51 30
nadia.bianco@keyrus.be



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Consulting & Staffing



2

Clinical Trials Management



3

Functional Services Platform



4

Real-world Evidence



Digital Enablement



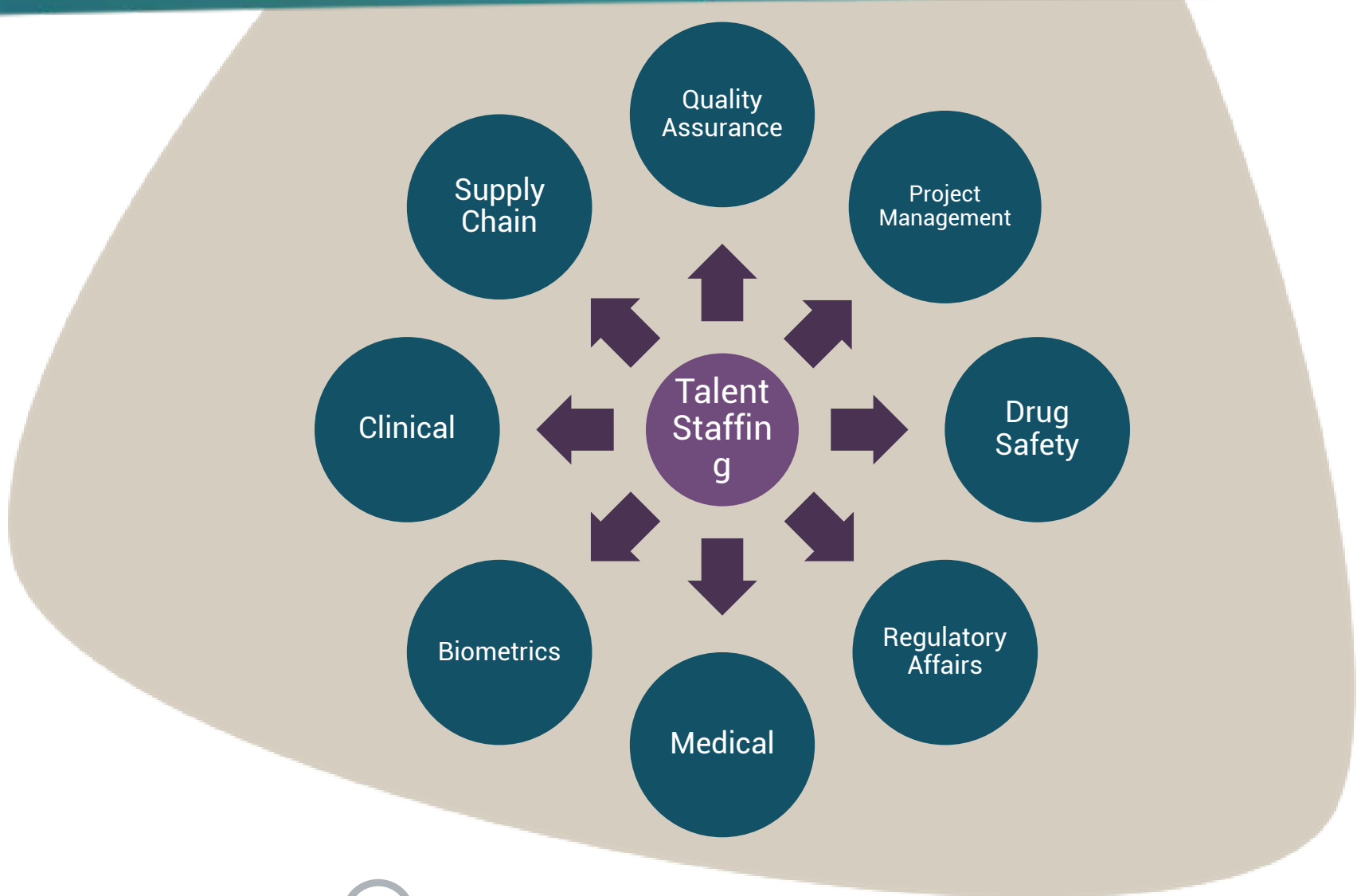
Life Data Science

The C²RO

Consulting & Staffing



experts
talent pool
short- and long-term



FUNCTIONS IN BIOTECH INDUSTRY – KEYRUS LIFE SCIENCE PROPOSE

PHARMACOVIGILANCE

- Drug Safety Scientist
- Drug Safety Physician
- Safety Database Administrator
- Drug Safety Coordinator

HEALTH ECONOMICS

- Health Economics scientist
- Epidemiology Scientist
- Computerized System Manager

QUALITY ASSURANCE

- Quality Assurance Officer/Manager
- QA GMP Specialist

MEDICAL AFFAIRS

- Medical Writer
- Medical Advisor
- Medical Information Specialist

CLINICAL OPERATIONS

- Clinical Research Associate
- Clinical Trial Assistant
- Clinical Project Manager
- Clinical Supply Manager
- Clinical Supply Assistant

STATISTICS

- Statistical Programmer
- Biostatistician
- Non-clinical statistician

DATA MANAGEMENT

- Study Data Manager
- EDC Designer
- Data Management Team Leader
- Data Entry Operator
- Analyst Programmer
- Data Manager Pre-clinical

REGULATORY AFFAIRS

- Regulatory affairs Associate/Manager
- Regulatory Affairs support/officer
- Technical Regulatory Writer

PROJECT MANAGEMENT

- Project Manager
- Project Director



COMPETENCIES OF OUR TALENT POOL

CLINICAL OPERATIONS

- Conduct of international studies all phases
- Coordination of monitoring activities
- E-CRF
- Follow-up of budget, forecast
- Submission of clinical trial applications to regulatory authorities and follow-up
- Submissions to EC
- Data entry

PHARMACOVIGILANCE

- Good knowledge of new EU PV regulation (GVP)
- Manage data included in ICSR (Individual Case Safety Report) collected from clinical trials, spontaneous sources, literature
- Coordination, review and approval of safety aggregate reports: DSUR, PSUR...
- Medical assessment, monitoring and evaluation of the risks associated with the use of a medicine

MEDICAL AFFAIRS

Medical information, medical advisor

- Management of medical queries from Healthcare Professionals
- Veeva Vault expertise
- Development of promotional materials
- Organization of congresses, events with KOL
- Product trainings

Publishing

- Publication of scientific data and study results
- Synthesize literature review findings into reports in various therapeutic area



COMPETENCIES OF OUR TALENT POOL

REGULATORY AFFAIRS

- Provide regulatory advice
- CMC writing and follow-up
- Preparation and submission of registration files, renewal applications, variations, line extensions
- Liaison with regulatory agencies
- Artwork review, FMD compliance

QUALITY ASSURANCE

- implementation of a Quality Management System
- Batch release
- Change Control
- Support to product transfer
- Management of CAPA's
- Product quality review

DATA MANAGEMENT

- Data entry
- Writing of Data Validation Plan
- Programming validation tests
- Management of queries
- Quality control of data
- Medical data coding
- Database lock
- Data mining techniques
- Expertise in SAS, R, Tableau, SQL

PROJECT MANAGEMENT

- Prince 2 certification
- 6-Sigma certification
- Management of projects from initiation to closing
- Budget & timing management
- Process improvement
- Communication with stakeholders

KEYRUS
life science



**HOW CAN WE HELP YOU ?
DON'T HESITATE TO CONTACT US**

The C²RO