EUROPEAN CENTRE FOR
CLINICAL RESEARCH TRAINING

Orienting your Career in Clinical Research

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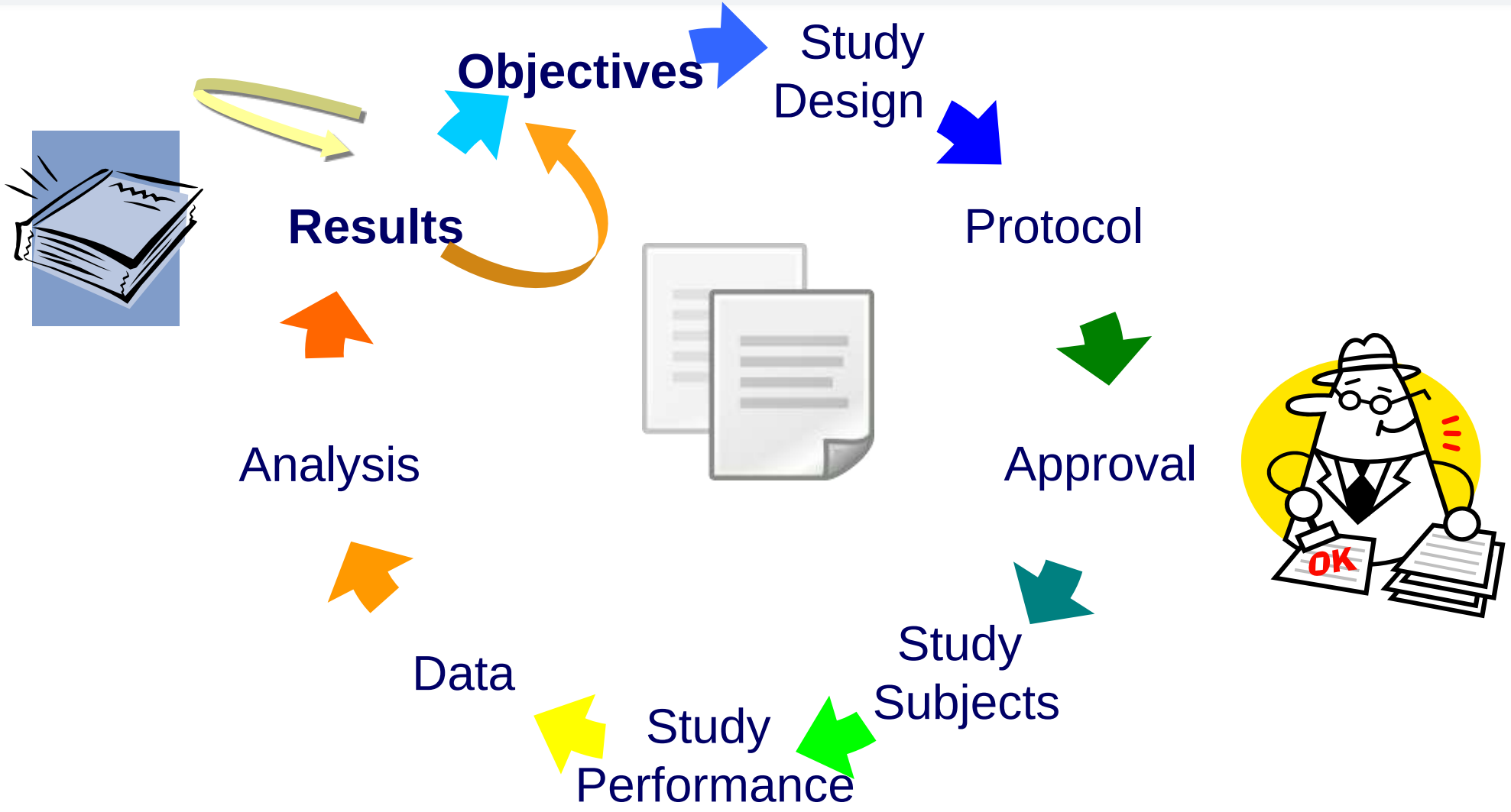
Existing positions in Clinical Research

The Clinical Trial Cycle



Training Talent

Job functions in clinical research

Objectives → Study Design → Protocol

Clinical Development
- Scientific writers
- Medical Writers

Job functions in clinical research

Regulatory Department

- Submissions to EC and CA
- Submission for MA

Approval

Job functions in clinical research

Clinical Sites
- Investigator
- Study Coordinator
- Study Nurse

Clinical Operations
- Clinical Research Associate
- Clinical Trial Administrator
- Project Manager

Quality Assurance
- Auditor
- QC Associate

(GCP, GLP, GMP)

Data

Study Subjects

Study Performance

Job functions in clinical research

Analysis

Data

Biometrics Department
- Data Management
- Data Entry, Analysis
- Statistical Analysis

Job functions in clinical research

Results

Analysis

Medical Writing

- Medical Writer

(writing of clinical study report)

Job functions in clinical research

And:

- IMP Handling
- Ancillary services (IVRS, Laboratory, Reading centre…)
- Pharmacovigilance
- Clinical Trial Physician
- Feasibility & Start-up functions
- Contract & Budget management

And many others…

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Who?

- A lot of players within a Clinical trials:
  - Sites (Hospitals, University institutes, non-profit research centre, etc.)
  - Regulatory bodies (EC, CA etc.)
  - Clinical Research organisation (CRO)
  - Sponsor (Pharmaceutical companies, academic bodies, investigators etc.)
  - Vendors: Central lab, IVRS (In-Voice Response System), central readers etc.

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Who?

- At sponsor/Clinical Research Organisation (CRO) site it is a multidisciplinary team coordinate by the PM:
  - Data Management
  - Statistician
  - Pharmacovigilance/safety
  - Regulatory
  - Legal
  - Finance
  - Etc.

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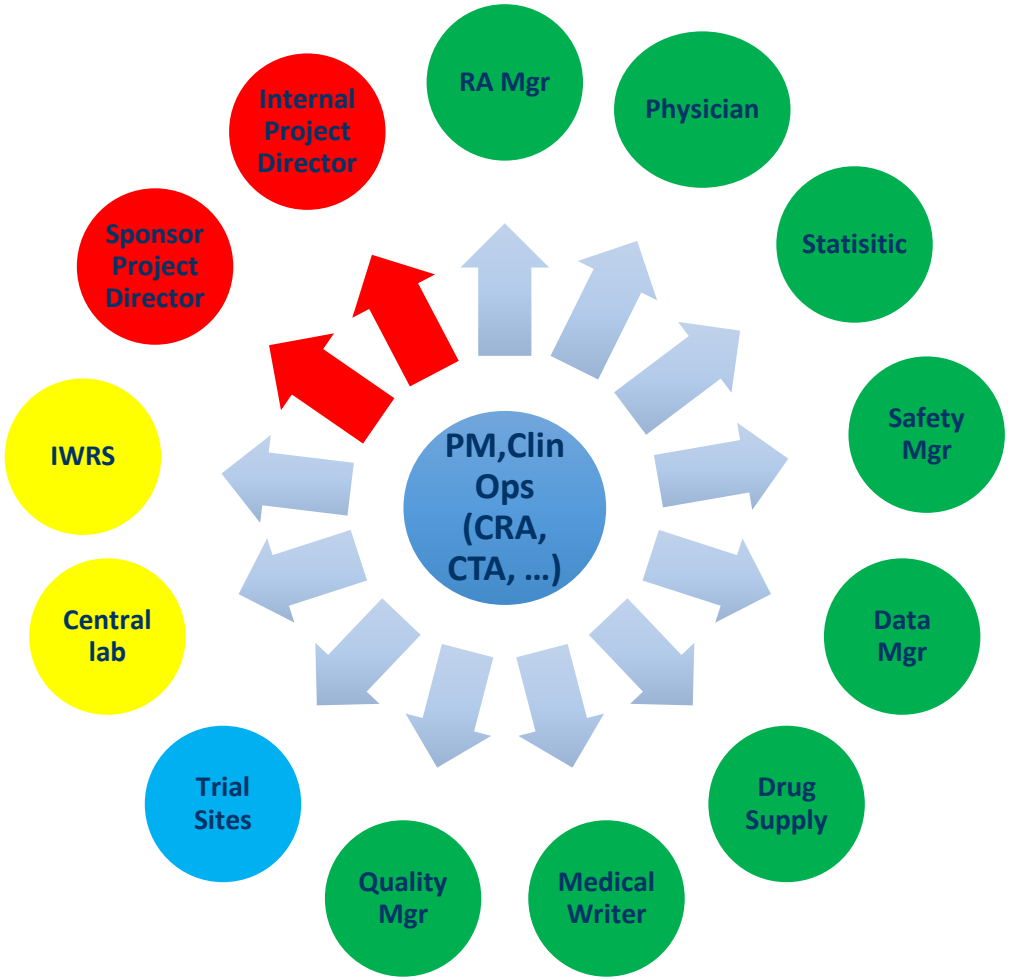
Global Trial Team



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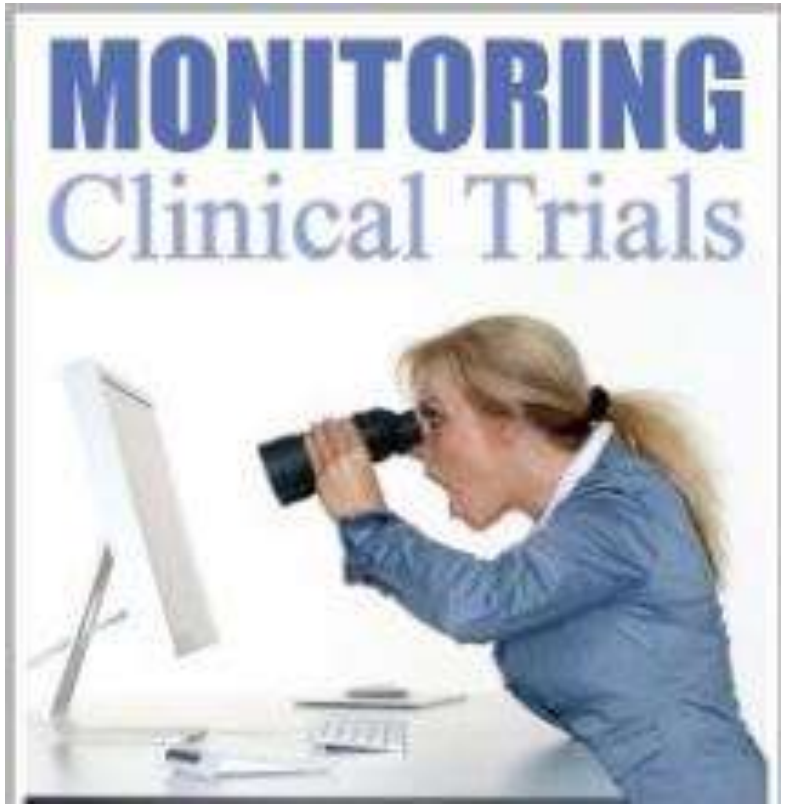
Project Manager

So what does a Project Manager need to do in practice?

a. Gain approval for the project scope & goals
b. Ensure a feasibility study is complete
c. *Select a team: delegate tasks & set individual objectives*
d. Plan the project in appropriate detail within time
e. Prepare the Project Plan in multidisciplinary team effort
f. Control and monitor the work and cost
g. Motivate, coach, lead the team
h. Report progress back to the organisation
i. Help the team to solve project problems
j. Achieve, with the team, the goals
k. Review and close down

PM Skills

- PM should be able to play with all trackers in order to sort out successes and threats
- Good in budget management
- Good communicator in order to coordinate the team (mainly virtual with internal and external stakeholders)
- Good in problem solving
- Good in reporting to sites, CRAs/Local, other departments, CRO/vendors and upper mgt.



Clinical
Research
Associate

The Sponsor: Monitoring ICH-GCP 5.18.1

Monitoring in theory:

- Verify if rights & wellbeing of each trial subject is respected
- Verify that reported data is accurate, complete & verifiable from source documents
- Verify that the conduct of the trial is in compliance with protocol, GCP, regulatory requirements

Monitor/CRA

- Monitoring in practice = monitor **checks** if:
  - INV supervises the team on site, i.e., team is adequately informed, performs trial specific functions
  - INV did not delegate functions to unauthorised individuals
  - INV enrols only eligible subjects
  - INV follows the study protocol
  - INV completes/updates/maintains source and trial records accurately, completely, legibly, timely and dated
  - INV follows up on action items
  - ……

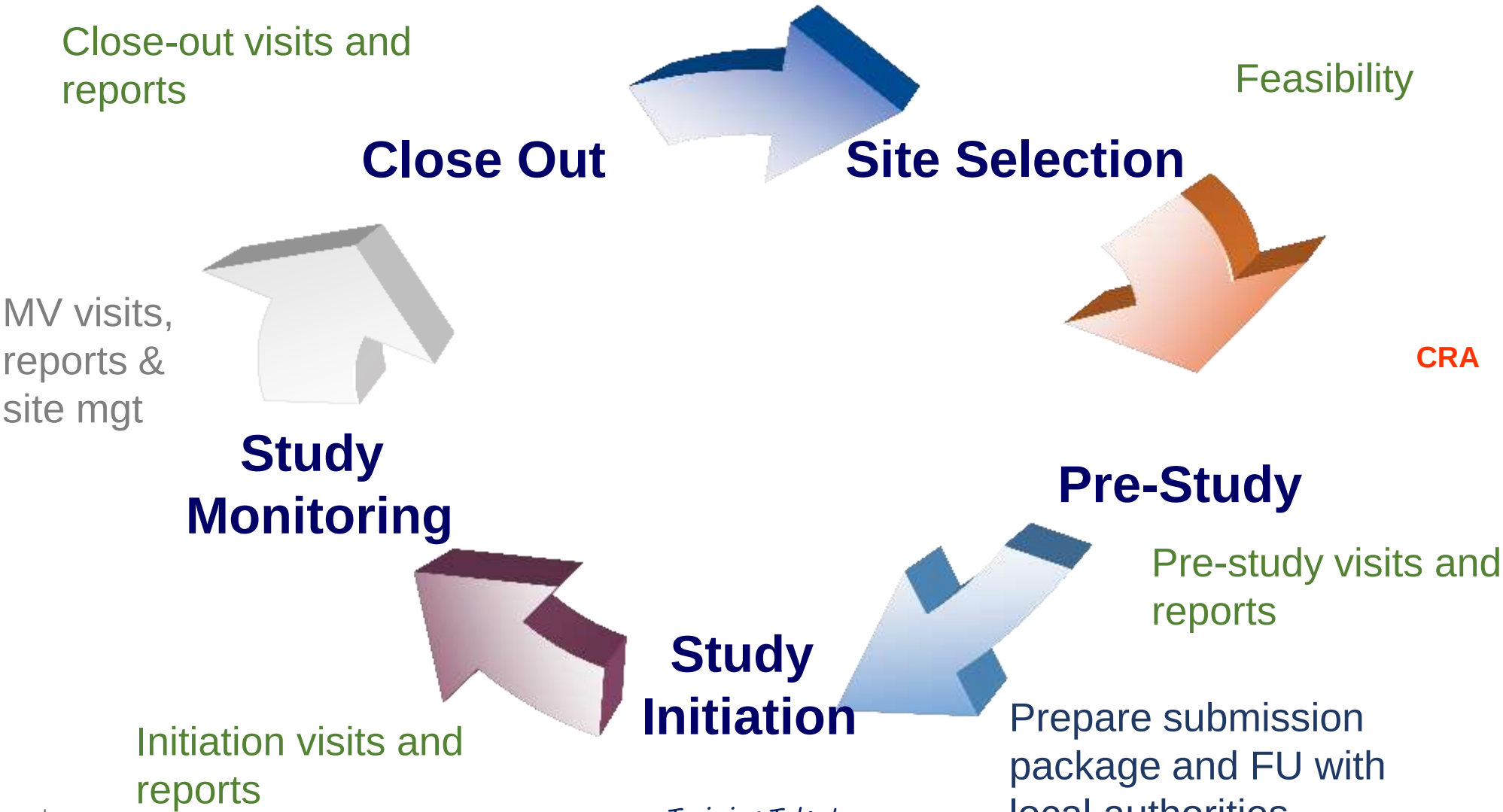
Site Management

- Keep team informed & be informed
  - Keep track of recruitment, of problems
  - Inform study team about any problem, indicate actions and follow-up until solutions
  - Follow-up outstanding matters asap
  - Inform, motivate & support the investigator and his/her study team
  - Escalate to manager poor performing / persistent non-compliant sites

Site Management

- Continuous and open communication are key for collaboration, flexibility professionality and for success of any clinical trial.

CRA tasks during Project life cycle



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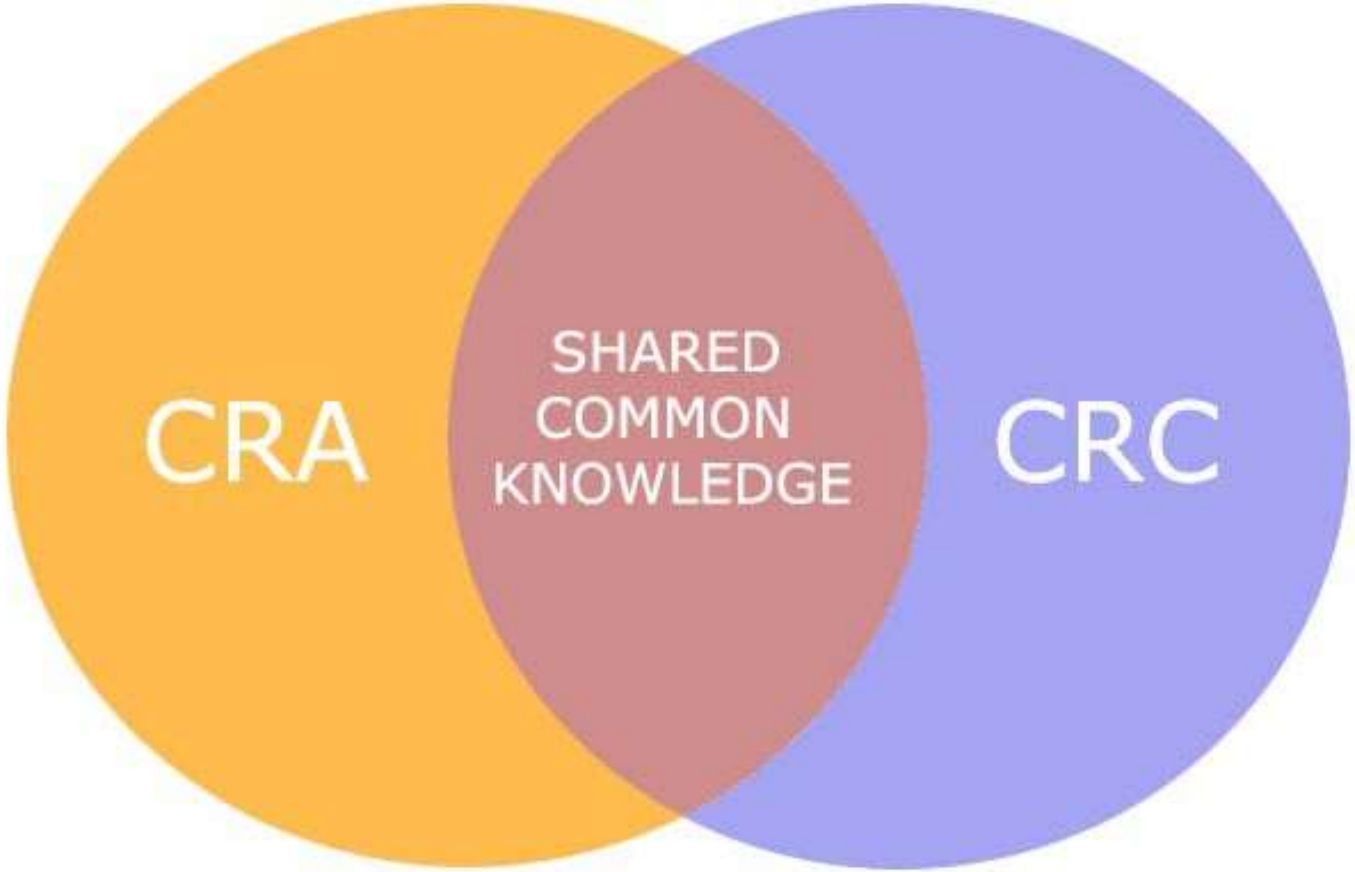
CRA skills

- Scientific background
- Flexible
- Good site comprehension
- Good data analyst
- Good with filing
- Good communicator
- Willing to travel



Clinical
Research
Coordinator

Clinical Research Coordinator

- Hospital based
- Coordinating studies on site
  - Planning & organising patient ’s schedules & assessments
  - Making sure the protocol is being followed
  - Making sure the data are collected
- The main counterpart for the CRA

CR Logistics & Supportive activities

- Site logistics
- Sample logistics
- Data collection
- Analytical services/labs

CR Logistics & Supportive activities

- Sites:
  - needs people to managed patients visits, study procedures (i.e. blood sample collection, X-ray, …) etc.
  - Materials: computer, centrifuge, fridge, binders etc.
  - Medication storage facilities
- Treatment:
  - Courier(dry ice, control temperature, timelines etc.)
  - Depots
  - Custom clearance etc.

CR Logistics & Supportive activities

- **Samples**
  - Materials for sample processing
  - Courier (dry ice, control temperature, timelines etc.)
  - Facilities to analyse samples (method, material etc.)
  - Facilities for storage
  - Ensure patient data reconciliation
- **Data collection system**
  - Case Report Form (CRF) either paper or electronic
  - IxRS for the patient randomisation and treatment management
- **Analytical services/Labs**
  - Central Laboratory
  - Analytical laboratories
  - Reading centres (e.g. ECG, radiological images, etc.)

Quality Assurance in pharma industry

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Quality Assurance in Pharma Definition

Quality

- **"Degree to which a set of inherent characteristics fulfils a set of requirements."**
- "The quality of an object can be determined by comparing a set of inherent characteristics against a set of requirements.
- If those characteristics meet all requirements, high or excellent quality is achieved but if those characteristics do not meet all requirements, a low or poor level of quality is achieved.
- So the quality of an object depends on a set of characteristics and a set of requirements and how well the former complies with the latter."
- *ISO 9000 – Terms and definitions*

Quality Assurance in Pharma
QA versus QC

QA

Independent of the process
Sampling
By QA representative

QC

Part of the process
Continuous / day to day
By operational staff

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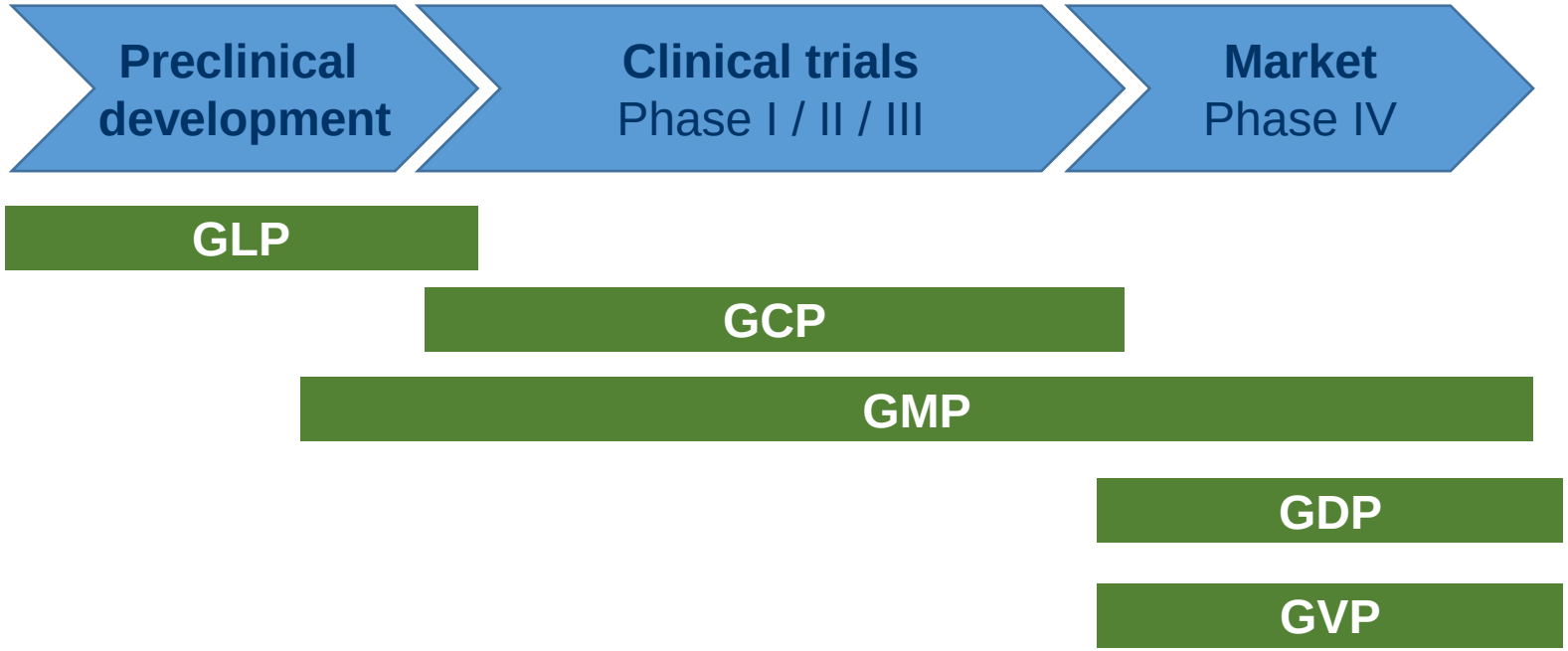
INTRODUCTION
Quality norms and standards

ICH

International Conference on Harmonization guidelines



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QA ACTIVITIES IN PHARMA

QUALITY POLICY
QUALITY STRATEGY, RISK MANAGEMENT, QUALITY REVIEW

QUALITY DOCUMENTATION SYSTEM

TRAINING

CONSULTING

SYSTEM / EQUIPMENT VALIDATION

AUDITS

INSPECTIONS

Training Talent

PROFILES REQUIRED FOR QA POSITIONS

- **Personal skills**

❑ Efficiency

- Precise and accurate
- Analytical skills and conceptual thinking skills
- Well-organised
- Time management and setting of priorities

❑ Self awareness

- Independent
- Pro-active
- Eye for details

❑ Interaction

- Excellent communication skills (verbal / written)
- Excellent training skills
- Diplomatic but firm / assertive

Regulatory Affairs

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Definition

Regulatory affairs (RA), also called **government affairs**, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, banking, telecom etc. Regulatory affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, biologics and functional foods).

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When regulatory Meets Clinical

- Regulatory Submissions
  - To authorities
  - To Ethics Committes
- Safety Reporting

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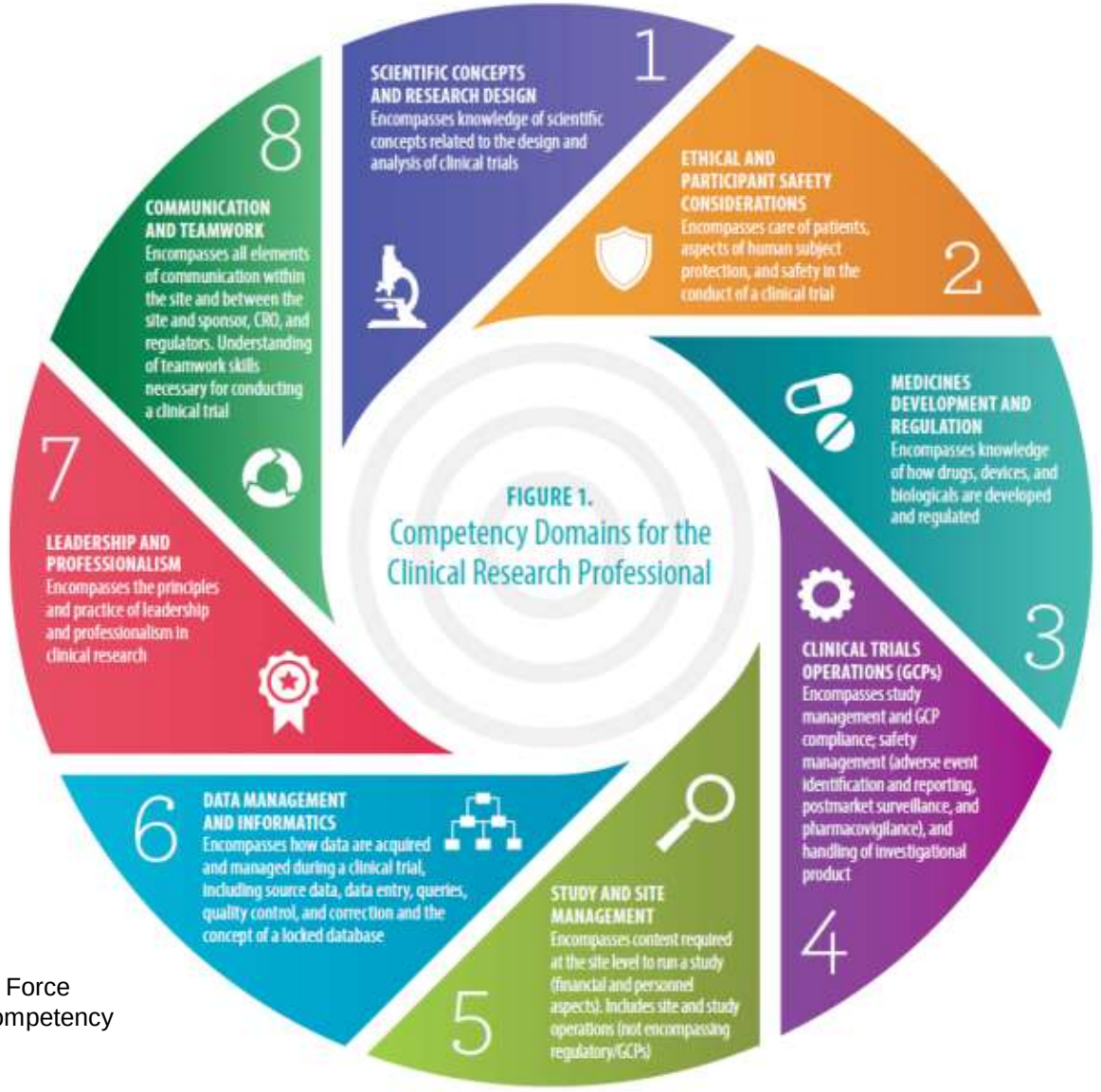
The Clinical Research Competency Framework

Clinical Research Competency Framework



Source: Joint Task Force for Clinical Trial Competency

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The Junior Clinical Researcher STAR Programme

THE GAP

- Graduates (MSc, PhD) are:
  - Well educated
  - Motivated
  - Gearing to get into the job market but with
    - **Limited or no practical experience**
- Companies want
  - Well educated, motivated staff but also with
    - **Practical experience**

Junior Clinical Researcher STAR Programme

Junior Clinical Researcher STAR Programme offers:

- **Introductory courses** bundled together
  - To be followed within one year but at a time that is convenient to you.
- **Practical traineeships** through the year
  - which gives you the possibility to acquire practical experience in the field and thus a kick-start of a brand new career in clinical research.

Junior Clinical Researcher STAR Programme

COURSES INCLUDE

COURSE TITLE	NUMBER OF DAYS
Introduction to clinical research	eLearning
Orienting your career in clinical research	0.5
ICG-GCP training	eLearning
Clinical research training for junior CRAs	2
Communication skills	1
New: from Dec 2016: Basics on regulatory requirements in clinical research	0.5

Traineeship

- **Hospital (~2 months):**
  - How is clinical research conducted in real life? How does it affect a patient?
  - What is the difference with the regular clinical practice?
- **Pharmaceutical/Medical Device Company (~6 months):**
  - How are Medicines developed?
  - Where does Clinical Research fit in the complete development.
  - Why is clinical research done differently from normal clinical practice?
- **Clinical Research Organisation (CRO) (~4 months):**
  - What activities need to be done in order to safeguard patients rights and wellbeing and at the same time make sure that quality of data obtained in a clinical study is guaranteed?

Traineeship Programme

- Traineeship programme is developed to build up the competencies required to start a job in Clinical Research field.

- ECCRT will
  - Get the participant enrolled in a Traineeship Programme
  - Coordinate the Traineeship
  - Closely mentor the participants through the entire traineeship programme.

Schedules

- The full programme runs 4 times per year.
- For more info, visit www.eccrt.com

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Thank you

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Questions ? Contact Us !

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