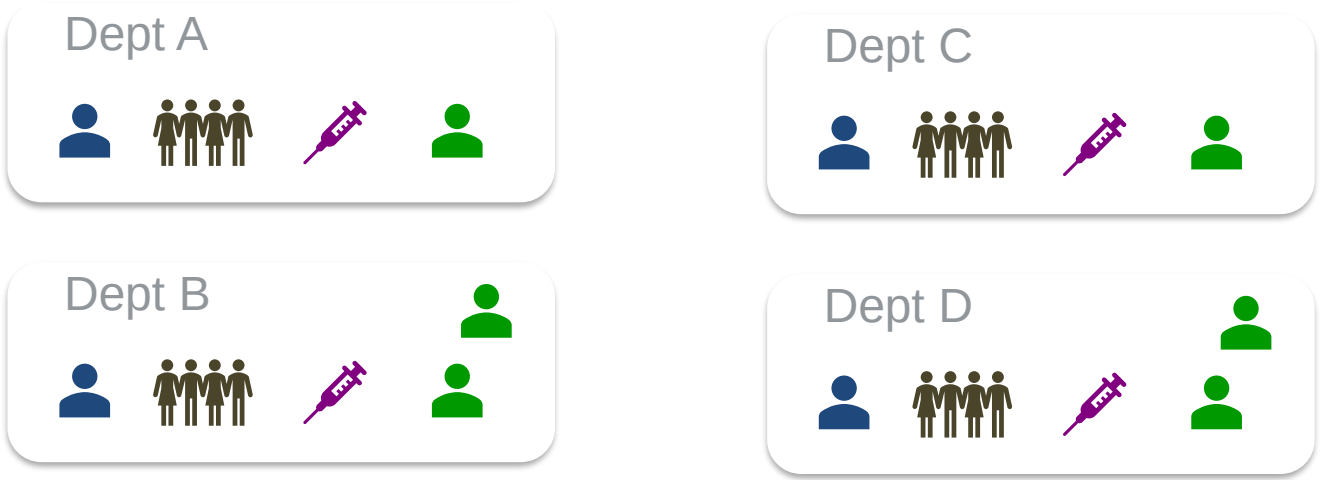
CAPACITAR | AÇÕES DE FORMAÇÃO E BENCHMARKING

AICIB AGÊNCIA DE INVESTIGAÇÃO CLÍNICA E INOVAÇÃO BIOMÉDICA

Atividades do Coordenador: um elemento central da Equipa de Investigação

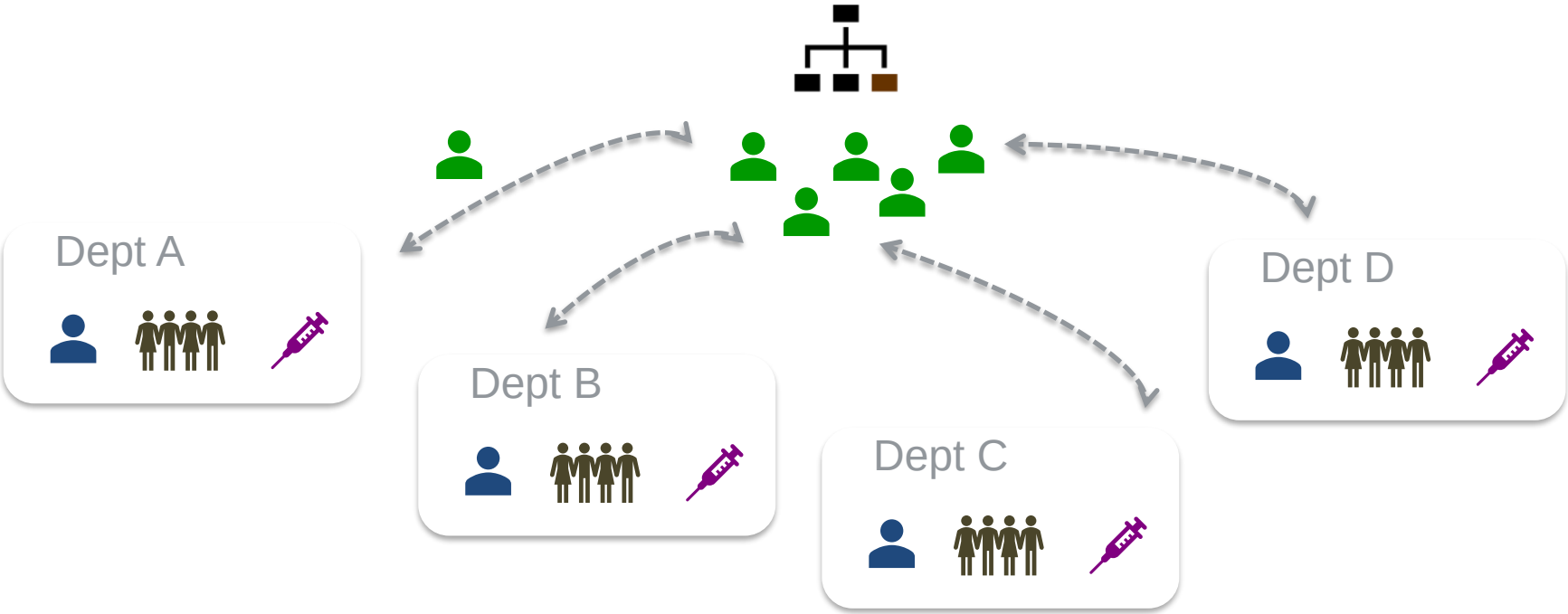
Sara Maia, PhD
NOVA Medical School- NOVA CRU

Organization of a Clinical Research Center



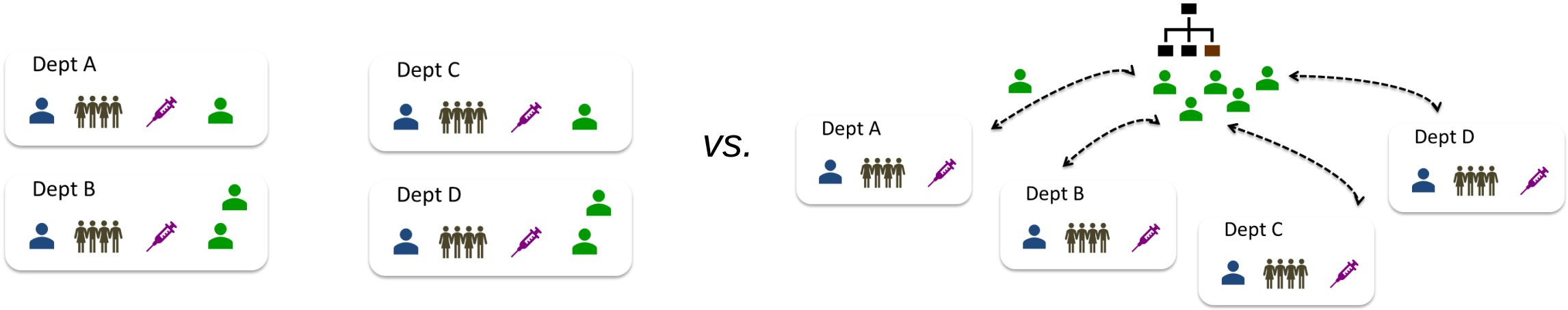
- Not centralized / Individualized
- No procedure harmonization
- Each Dept. has diferent SOPs (or no SOPs)
- Less organized
- Different circuits / documents / response times

Organization of a Clinical Research Center

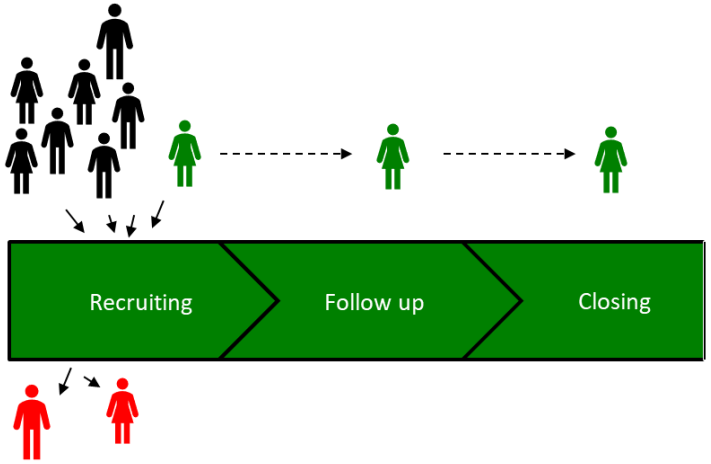


- Centralized
- Procedure harmonization
- Common SOPs
- More organized
- Common circuits / documents / response times

Organization of a Clinical Research Center



Clinical Research Process



COV
SMV
SMV
SMV
SMV
SMV
SMV
SIV
Training
Submission
Selection
Design

Clinical Research Stakeholders

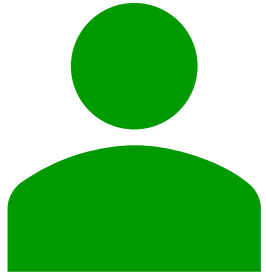
- Sponsor / CRO / CTU
- Principal Investigator
- Study Coordinator
- Research Department
- Administration Board
- Sub-Investigators
- Nurses
- Pharmaceutical Department
- Local Laboratory
- Other Departments / Units
- Financial Department
- Participant

ceic
Comissão de Ética para a Investigação Clínica
National Ethics Committee for Clinical Research

Local EC

infarmed
Autoridade Nacional do Medicamento
e Produtos de Saúde I.P.

Study Coordinator



Clinical Trial Coordinator

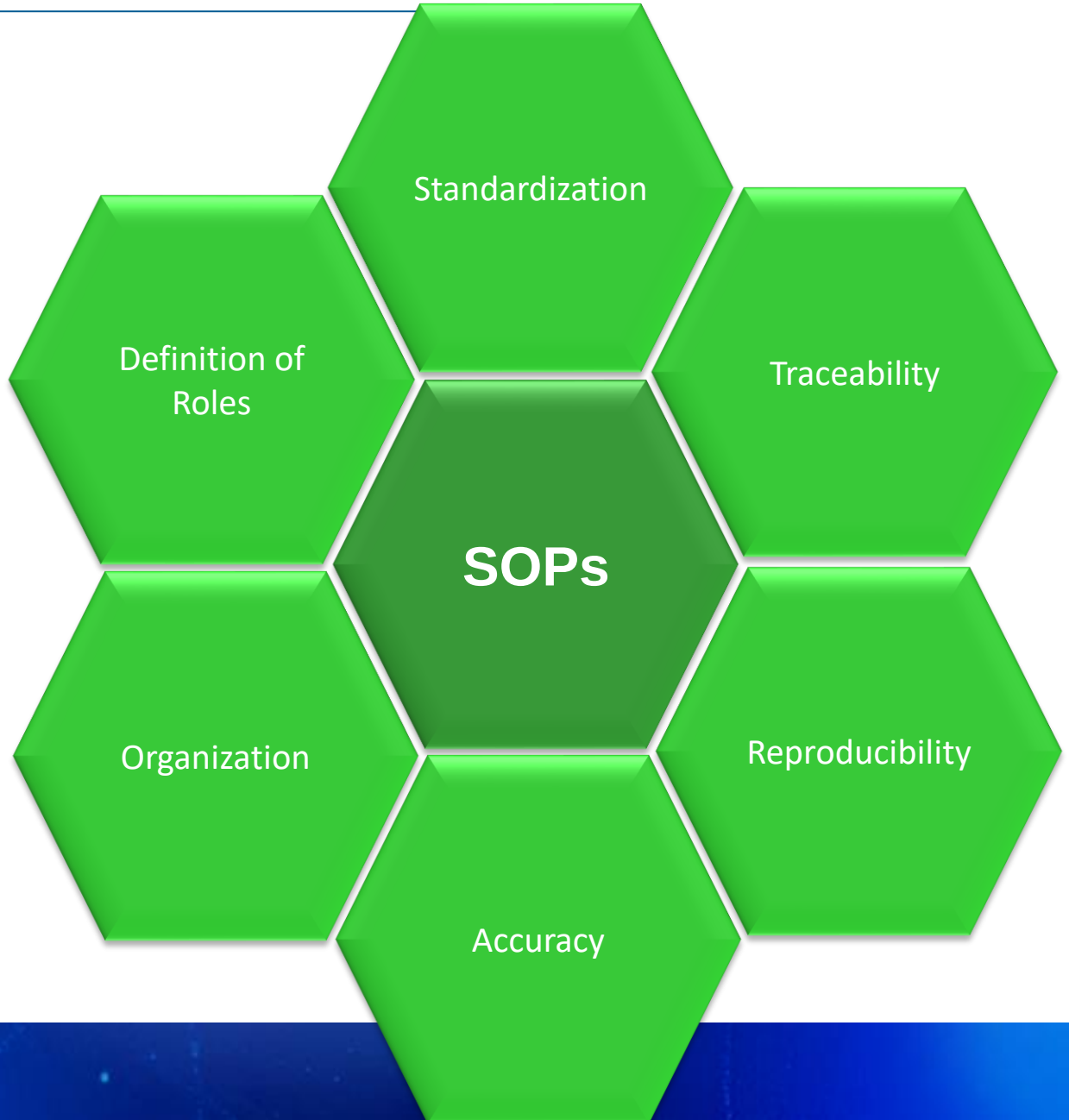
Clinical Research Coordinator

A study coordinator is a specialized person who supports the management and coordination of clinical research studies

Study Coordinators

- Management of all processes related to clinical studies
- Management of study players (sponsors, research teams, participants, administration board, etc)
- Educates staff, patients, and referring health care providers about the study
- Communicates regularly with the PI, other team members, sponsor
- **Assists** the PI/SI with the informed consent process, study monitoring, quality assurance, audits, and data management
- Prepares and follows-up participants' visits
- Data entry, query resolution

Study Coordinator as Quality Manager



Study Coordinator as Quality Manager

Development of Standard Operating Procedures (SOPs)

- Training: GCP, IATA, data entry, clinical research, team members, study protocol, …
- Selection: Feasibility / Qualification Process
- Study submission
- Elaboration of study documents
- Study conduct: ICF, AE classification and report, sample management, IP management, monitoring visits, ….
- Interaction with vendors (sample shipment, kits, exam up loads, etc)
- Development and maintenance of databases …..

O Centro de Investigação Clínica onde trabalha possui *SOP*s dedicadas à Investigação Clínica?

a. Sim

b. Não

Study Coordinator as Quality Manager

Development of Standard Operating Procedures (SOPs)

Contributes to…..

- Standard documents
- Standard procedures
- Distribuition of tasks
- Accountability
- Definition of timelines and objectives

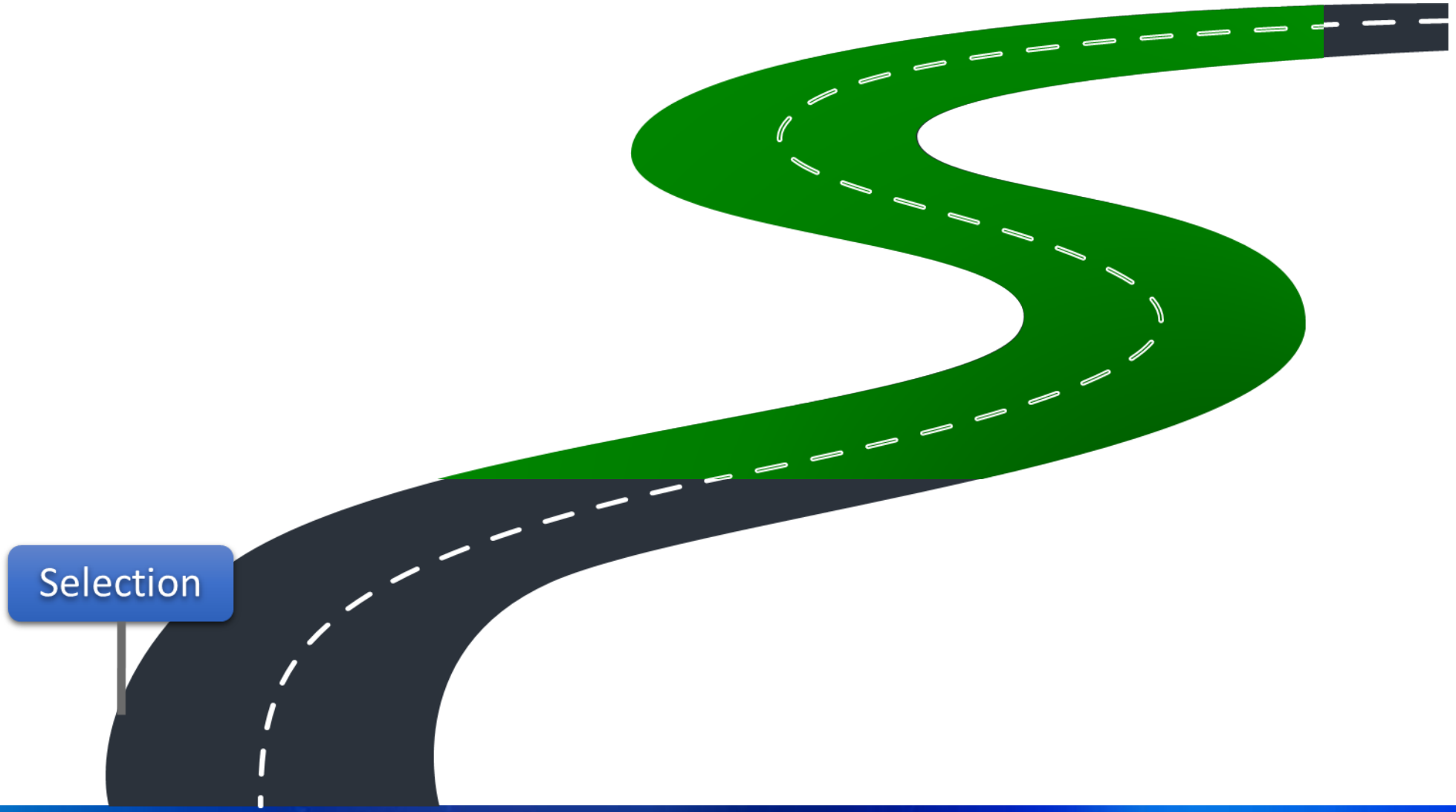
✓ **Structure**

✓ **Organization**

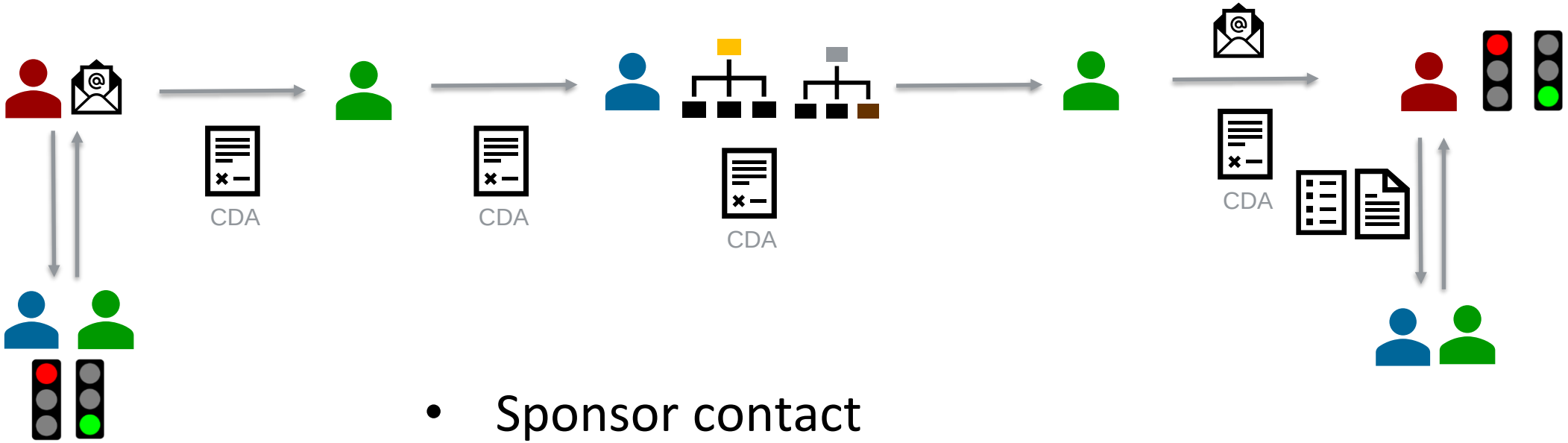
✓ **Profissionalization**

of Clinical Research

Study Coordinator as a Site Selection Specialist



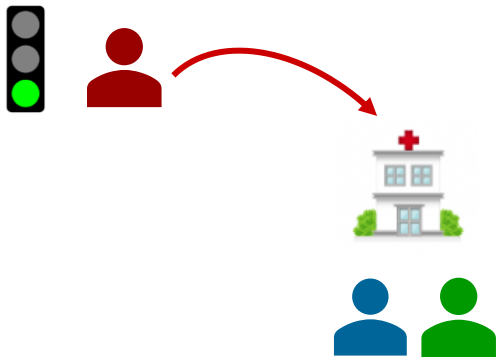
Study Coordinator as a Site Selection Specialist



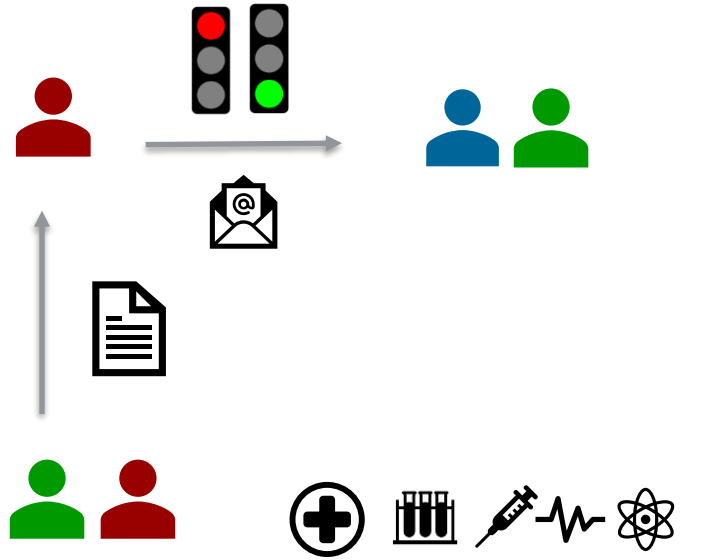
- Sponsor contact
- CDA
- Questionnaire
- Synopsis
- Schedule of Assessments

Study Coordinator as a Site Selection Specialist

Site Qualification Visit (SQV)



- Feasibility questionnaire discussion
- Remote / In-site
- If in-site, visit to site facilities
- Collection of documents



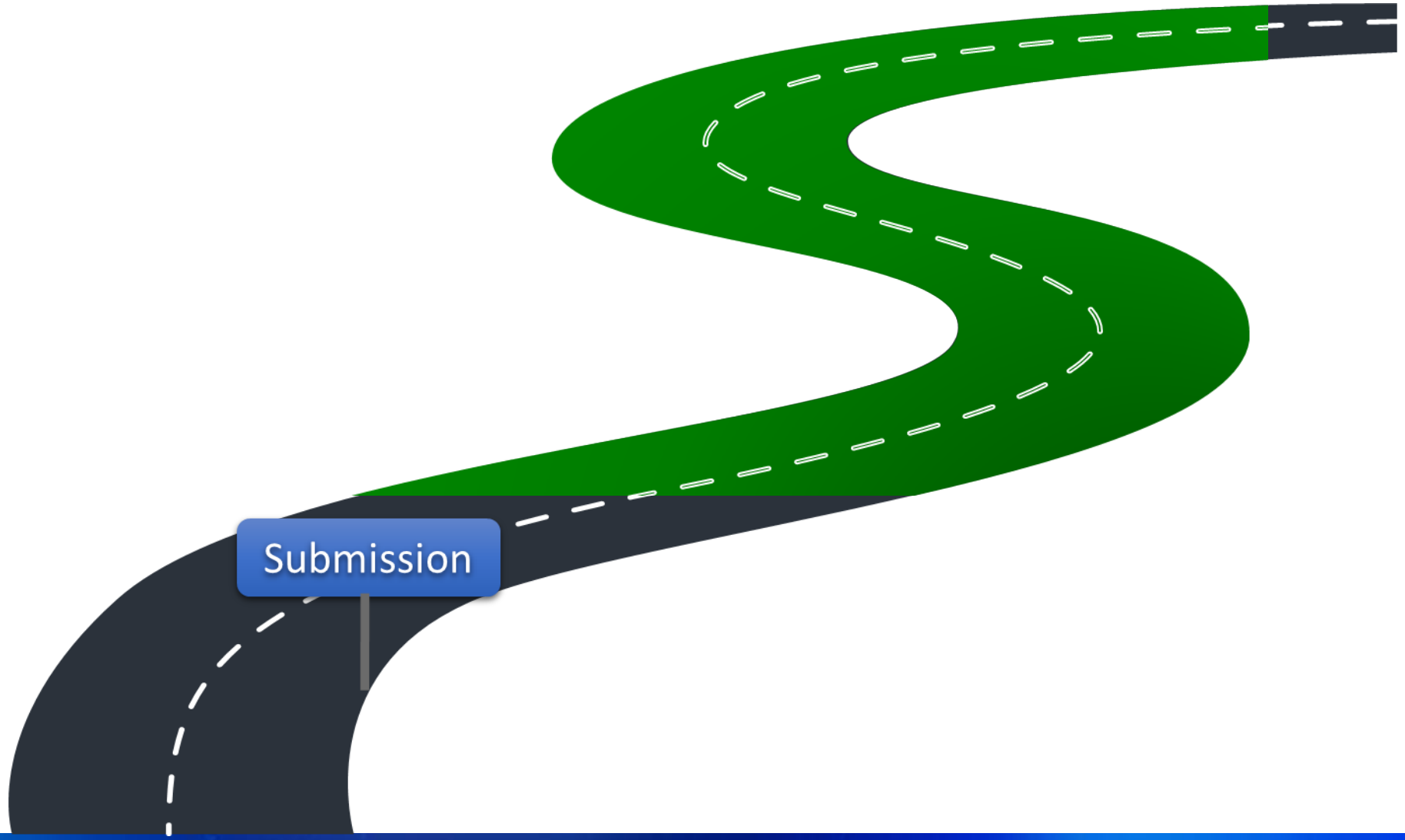
Local Lab
Pharmacy Department
Radiology Department
Etc

Factors that Contribute to Site Selection

Systematic planned process to evaluate and select an investigator and site for conduct of clinical trial:

- Reputation in field
- Facilities desirable for trial conduct
- Access to patient population
- Anticipated time for initiation and completion of trial
- Budgetary factors
- Site Performance (protocol compliance, recruitment, GCP compliance, reply to sponsor)
- Ability to process protocols fairly and expeditiously
- Site organization

Study Coordinator as Start Up Specialist



Study Coordinator as Start Up Specialist

Estudos / Entidades		Comissão de Ética Competente		Autoridade Regulamentar		Centro de Investigação Clínica (CIC)
Intervenção	Tipo de Estudo	Parecer Favorável da CEIC	Parecer Favorável da CES	Autorização Favorável do *CTIS*	Autorização ou Notificação do INFARMED	Autorização do CA/CD
Com Intervenção	Ensaio Clínico	X		X	X	X
	Estudo de Investigação Clínica com Dispositivo Médico	X			X	X
	Estudos Clínicos de Produtos Cosméticos e de Higiene Corporal		X		X	X
	Estudos Clínicos com Técnica Cirúrgica		X			X
	Estudos Clínicos com Intervenção de Procedimentos		X			X
	Estudos Clínicos de Nutrição		X			X

- Legislation
- Required documents
- Players
- Communication
- Timelines

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Study Coordinator as Start Up Specialist

Estudos / Entidades		Comissão de Ética Competente		Autoridade Regulamentar		Centro de Investigação Clínica (CIC)
Intervenção	Tipo de Estudo	Parecer Favorável da CEIC	Parecer Favorável da CES	Autorização Favorável do *CTIS*	Autorização ou Notificação do INFARMED	Autorização do CA/CD
Sem Intervenção	Estudos Observacionais		X			X
	Estudos de Eficácia Pós-Autorização (*PAES*)	X			X	X
	Estudo de Segurança Pós-Autorização (*PASS*)	X			X	X

- Legislation
- Required documents
- Players
- Communication
- Timelines

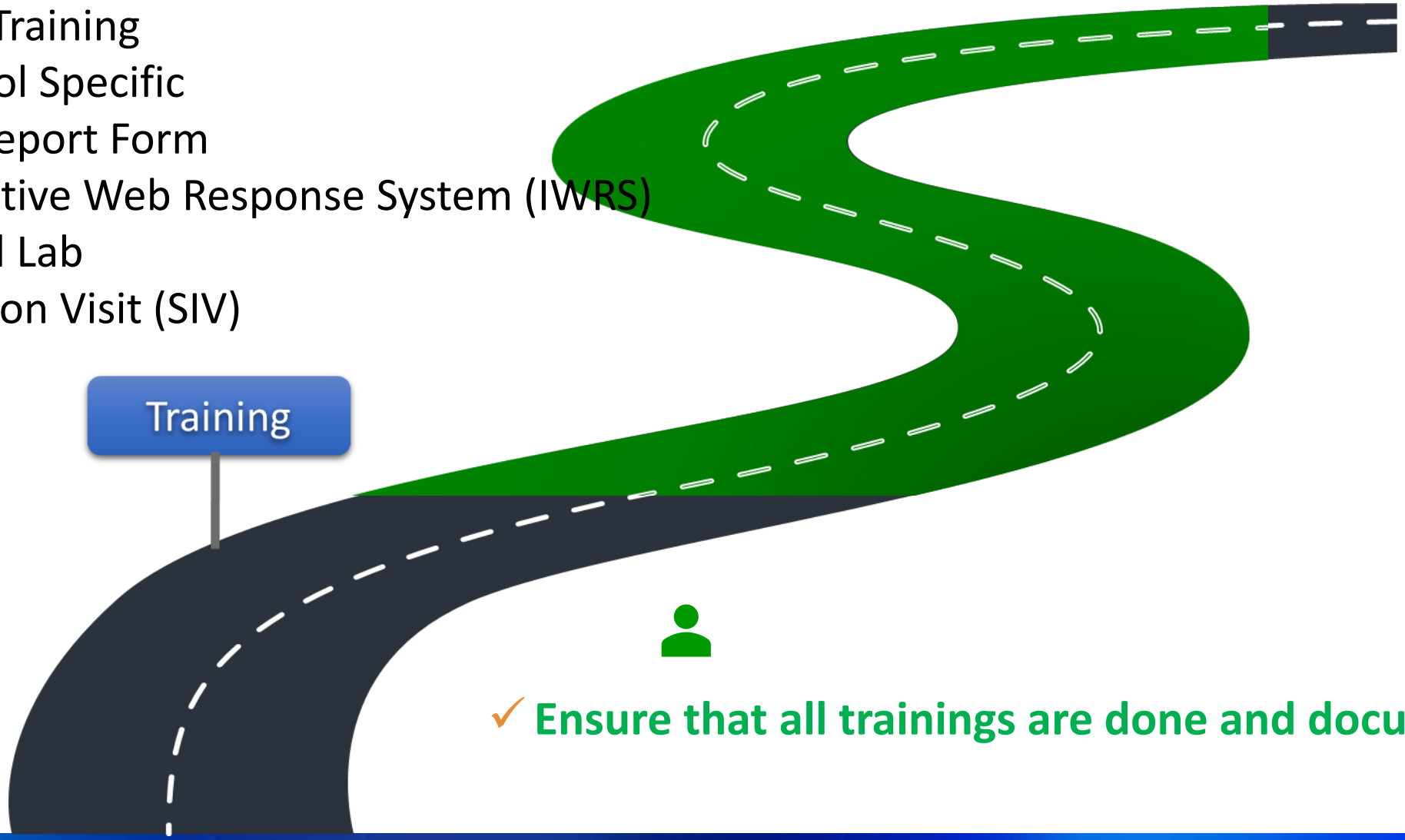
Study Coordinator as Start Up Specialist

Study specific preparation

- Protocol analysis (visits, procedures, SoA, AEs report, players)
- Identification of potencial participants
- Worksheets / forms (eligibility criteria, nurse procedures, etc)
- Participant calendars (when not available)
- Sample tracking forms
- Billing maps (visits, patient reeimbursments, team payment)

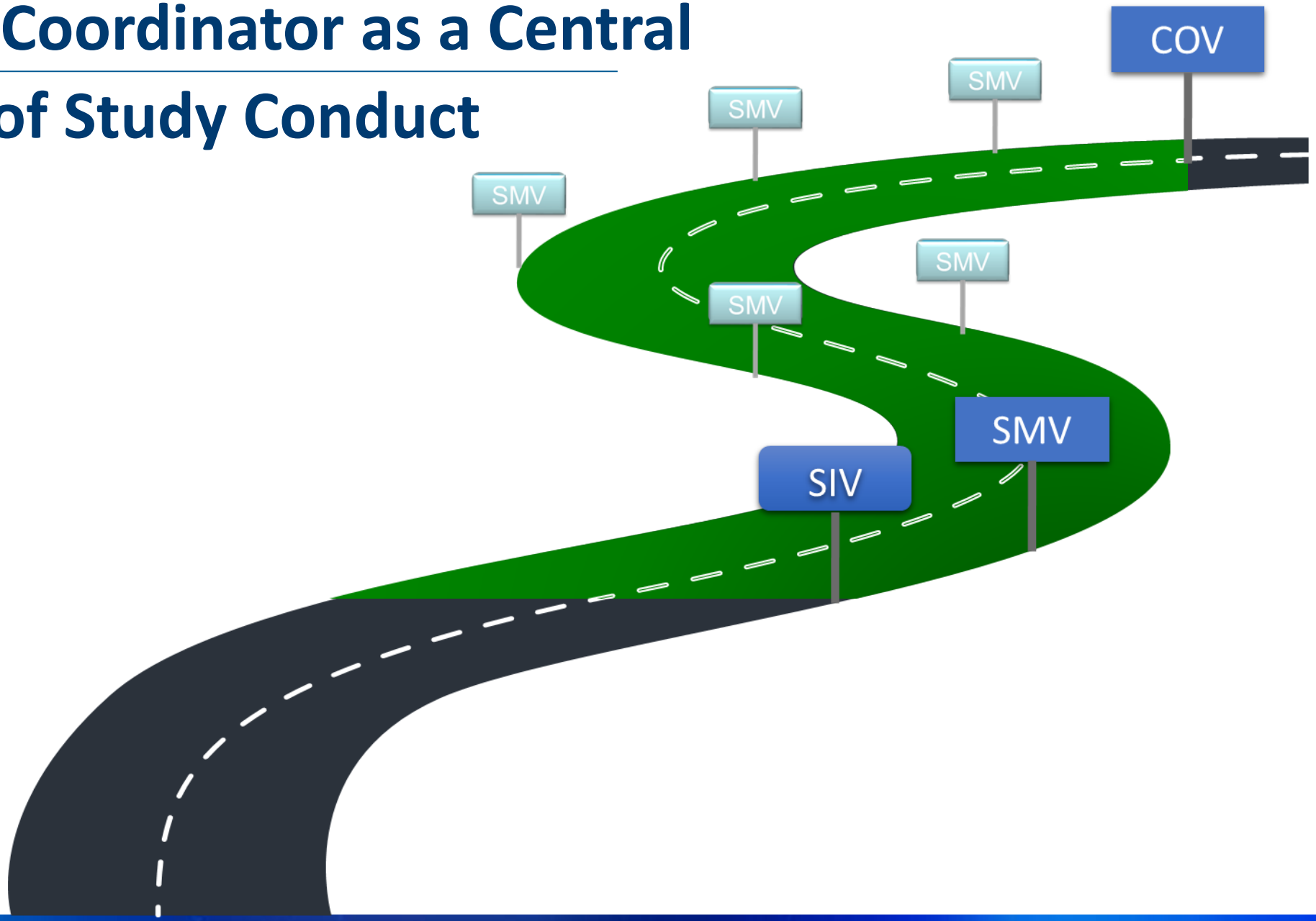
Study Coordinator as Start Up Specialist

- Investigator´s Meeting
- Platforms Training
  - Protocol Specific
  - Case Report Form
  - Interactive Web Response System (IWRS)
  - Central Lab
- Site Initiation Visit (SIV)

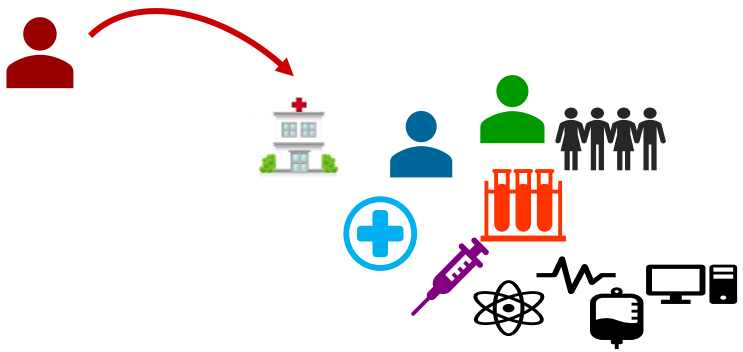


✓ **Ensure that all trainings are done and documented**

Study Coordinator as a Central Piece of Study Conduct



Site Initiation Visit /SIV)



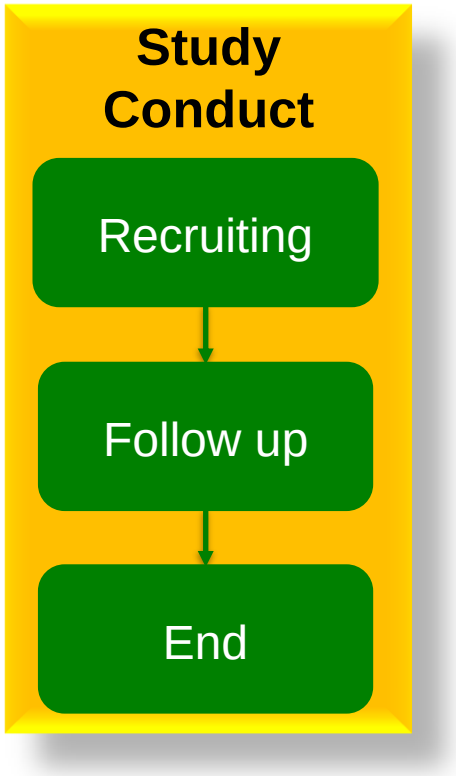
- Remote / On-site
- Protocol and procedures
- Study platforms, documents and materials
- Informed Consent Process
- AEs / SAEs
- Investigation Medicinal Product (IMP):
  - storage, randomization, logs, destruction
- Monitoring plan
- GCP-R2
- Training and Delegation log

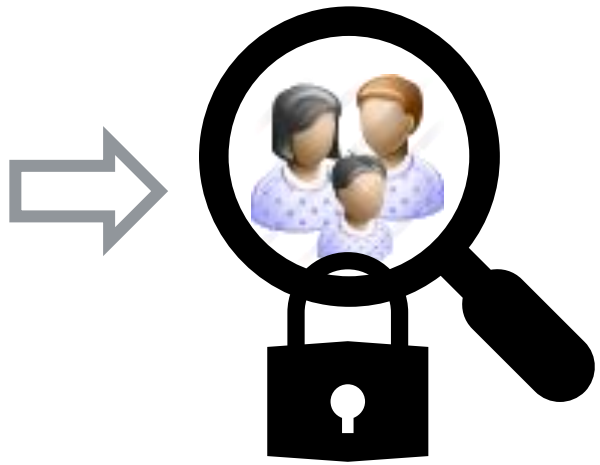
✓ **Ensure the presence of all team members**

✓ **Ensure that all equipment and materials are in the Center**

✓ **Ensure that all documentation is collected and signed**

Study Coordinator as a Central Piece of Study Conduct





http://www.appliedclinicaltrialsonline.com

Study Coordinator as a Central Piece of Study Conduct

VISITA DOS PARTICIPANTES

ANTES da VISITA

-Agendamento e Confirmação da Visita

-Aviso da Equipa de Investigação e do Participante

-Marcação de consultas e de exames previstos em Protocolo

-Preparação do dossiê do Participante

-Envio do Guião para o Investigador

-Verificação de todo o material necessário à Visita e preparação de Equipamentos

-Preparação de *Kits*

-Pedido de gelo seco e de recolha de amostras

-Marcação do transporte do Participante

DURANTE a VISITA

-Acompanhamento do Participante

-Verificação da *Checklist* de procedimentos

-Auxílio da Equipa nos procedimentos

-Dispensa/ devolução de medicação

-Avaliação da *compliance* com o Medicamento Experimental e procedimentos do Estudo

-Agendamento da Visita seguinte

-Auxílio no preenchimento do Processo Clínico do Participante

-Gestão de amostras biológicas

APÓS a VISITA

-Marcação do transporte do Participante

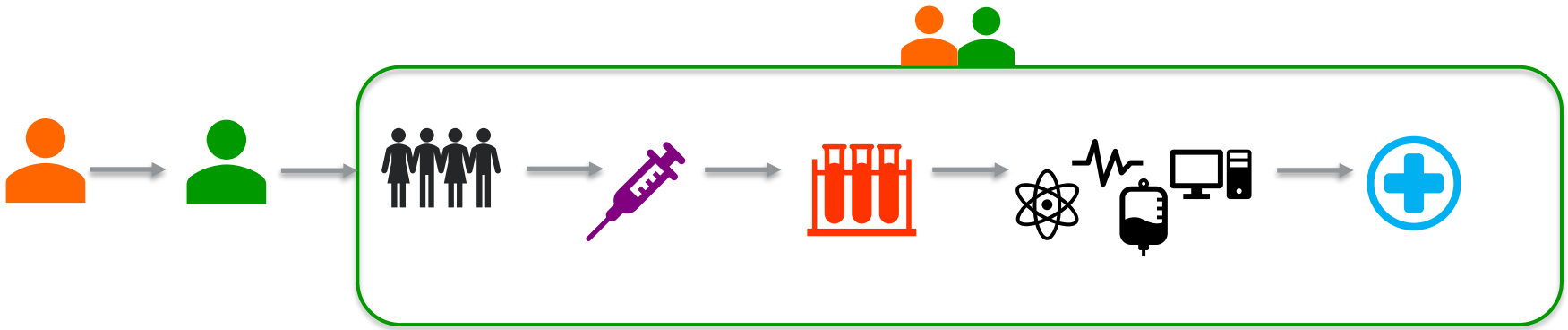
-Pedido de isenção de taxas moderadoras

-Envio das amostras

-Preenchimento de *CRF*

Daniela Abreu, 2022

Study Coordinator as a Central Piece of Study Conduct



- ✓ Ensure the all procedures are done accordingly to the study protocol
- ✓ Verify source documents
- ✓ Collect data with quality
- ✓ Ensure that visits are performed within expected time
- ✓ Patient expenses
- ✓ Fill in eCRF
- ✓ Data queries´ cleaning
- ✓ Report AEs and SAEs

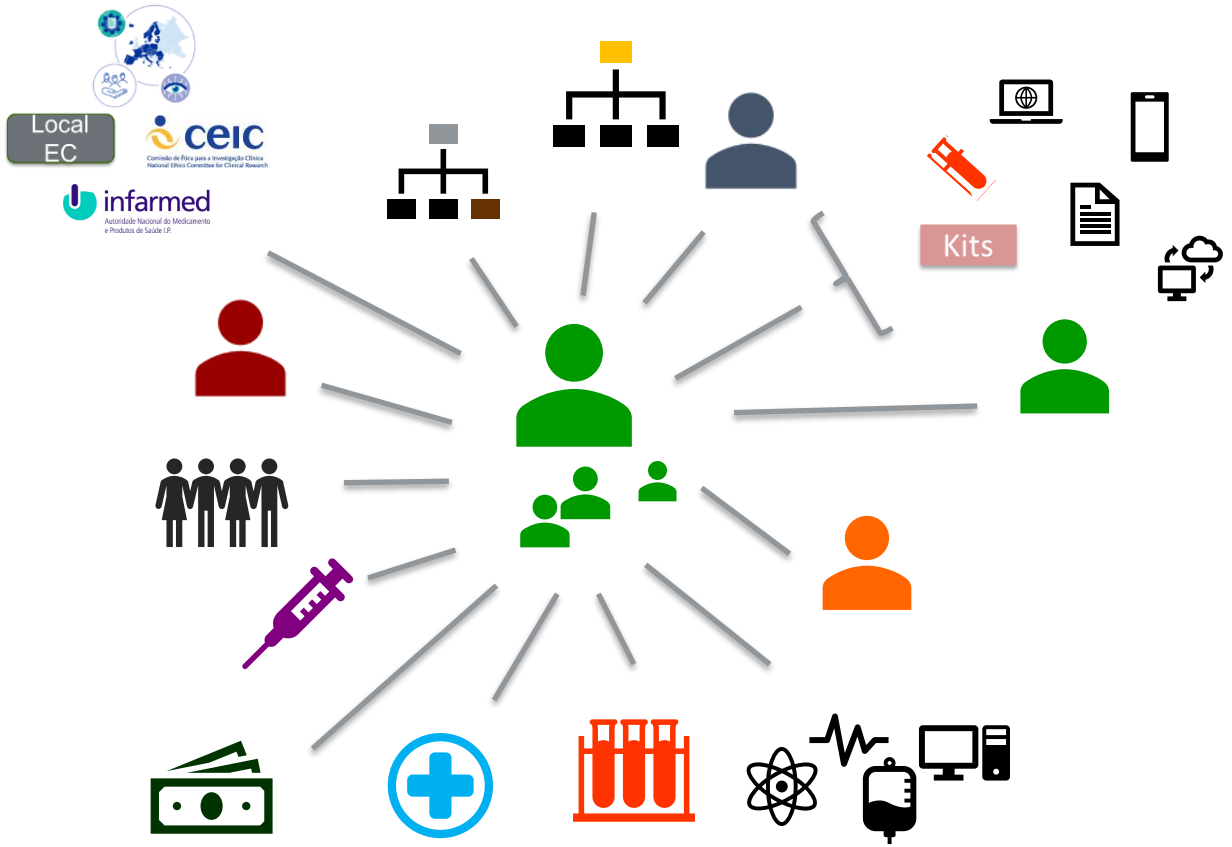
Recruit the proposed numbers of participants

Avoid dropouts

Enquanto Coordenador de Estudos, quais são as funções /tarefas que desempenha?

(assinale todas as opções aplicáveis)

A day of a Study Coordinator



Skills of a Study Coordinator

1. **Management**
2. **Communication**
3. **Coordination**
4. **Writing**
5. **Decision Maker**
6. **Active Learner**
7. **Speaker**
8. **Negotiation**
9. **Monitoring**
10. **Multi-task**
11. **Patience**
12. **Hard Working**
13. **Motivator**
14. **Instructor**
15. **Critical Thinker**
16. **Detail, detail, detail…**

Clinical Research Process

Reality

To sumarize…

- ✓ Study coordinators can perform various tasks / roles (depending on Site organization and their experience)
- ✓ Oversight of multiple clinical studies and teams
- ✓ Team member
- ✓ Like to interact with people
- ✓ Attention to detail
- ✓ Very organized

Daniela Abreu, 2022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