



Communication in clinical trial management

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Communication in clinical trial management

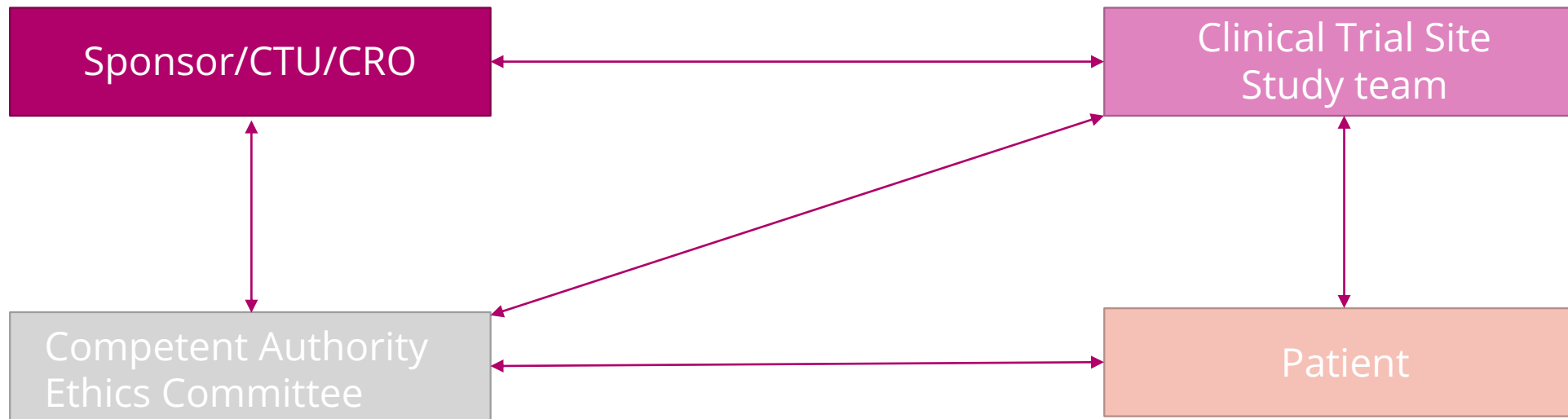
- **Communication:**
 - The exchange of information between persons
- Communication has three parts:
 - The sender
 - The message
 - The recipient/s
- One of the key factors in clinical trial management
 - Effective, clear, as short as possible

Communication in clinical trial management

- Who with whom?
- What communication methods?
- Why?
- When?

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Who with whom?



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Who with whom?

- **Sponsor/CTU/CRO**

- Project manager
- Lead Monitor/Monitor
- PV teams
- Medical reviewer
- Data manager/eCRF
- Lawyers
- Any other relevant specialist

- **Clinical Trial Site**

- PI
- SubI
- Study nurse
- Pharmacist
- Study coordinator
- Start-up manager
- Data manager
- Any other relevant specialist

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Communication methods

- There are **several** different methods of communication
- How you communicate depends on **who you are communicating with** and **the purpose** of that communication
 - Phone call
 - Writing form (emails, paper documents...)
 - Personal meeting (face to face meetings)
 - Meeting (personal/online)
 - Hybrid meeting
 - Other communication tools (e.g. chats, tools with live polls, Q&A...)
- Communication methods may vary depending on the subject of communication
- Try to avoid using SMS, WhatsApp in **official communication**

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Why?

- The **purpose** of that communication
- Who is the **relevant person** to obtain information?
- **Clear subject** of communication
 - Do not ask too many **different** questions in one email
 - Better to ask more questions in one email than to send 3-4 emails (can hide in the loop)
 - Meetings, send the agenda in advance
- Need to know the process (life cycle of the clinical trial)
 - **Nobody is an expert in all fields**
 - **Who why when and how**

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When?

- **Whenever necessary**
- Life cycle of the clinical trial
 - Start-up phase
 - Monitoring
 - Close-out
- *Ad hoc*
 - Any other purpose not strictly related to a specific clinical trial

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When?

- **Start-up phase**
 - Country feasibility
 - Centre feasibility
 - Pre-study visit
 - Regulatory / Contracting
 - Site initiation
- Sponsor wants to have a lot of information in a short time
- Study team needs to provide relevant feedback in a tight deadline
- **Effective communication has a key impact on the selection of a country / centre in a clinical trial, the design of the clinical trial, and the conduct of the clinical trial itself**

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When?

- **Start-up phase**
 - Country feasibility
 - Centre feasibility
 - Pre-study visit
 - Regulatory / **Contracting**
 - Site initiation
- Very often it takes a long time (a few months)
- Budget and terms of contract need to be discussed
 - Any issue needs to be solved in a short time
 - More persons involved in this process, good cooperation is needed
- National template of a Clinical trial Agreement
- Good workflow in an organization

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When?

- **Monitoring**
- **Close-out**
 - Communication between
 - Sponsor/CTU/CRO and study team
 - Study team and e.g. IMP supplier, central laboratory
 - Please always put the monitor in the Cc
 - The monitor should be aware of any activities/problems in the centre
 - A source of misunderstanding

Do we have effective communication?

- **Sponsor/CTU/CRO**

- Project manager
- Lead Monitor/Monitor
- PV teams
- Medical reviewer
- Data manager/eCRF
- Lawyers
- Any other relevant specialist

- **Clinical Trial Site**

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- **Contact person in each organisation**

- Recipient, but if not, must always be in the copy

Tips for effective communication

- Right persons
 - Depends on what you would like to know
- Choose the right method of communication
 - Email/phone call/TC
- Clear topic
 - Clear subject of the email
 - Clear topic of the TC
- **Ethics in email communication**
 - **Please keep people in Cc, please reply all**
 - If you are in Cc, it is just FYI

Take-home message

- One contact point to avoid duplication
- Need to know the internal/external process
 - You ARE NOT an expert in all fields, you need to ask right questions and know right persons
- Keep people in Cc
- Effective communication saves a lot of time
- Lack of communication can cause serious problems later

Thank you for your attention!
Any questions?

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