

Site Insights: What your clinical sites really think of your study processes



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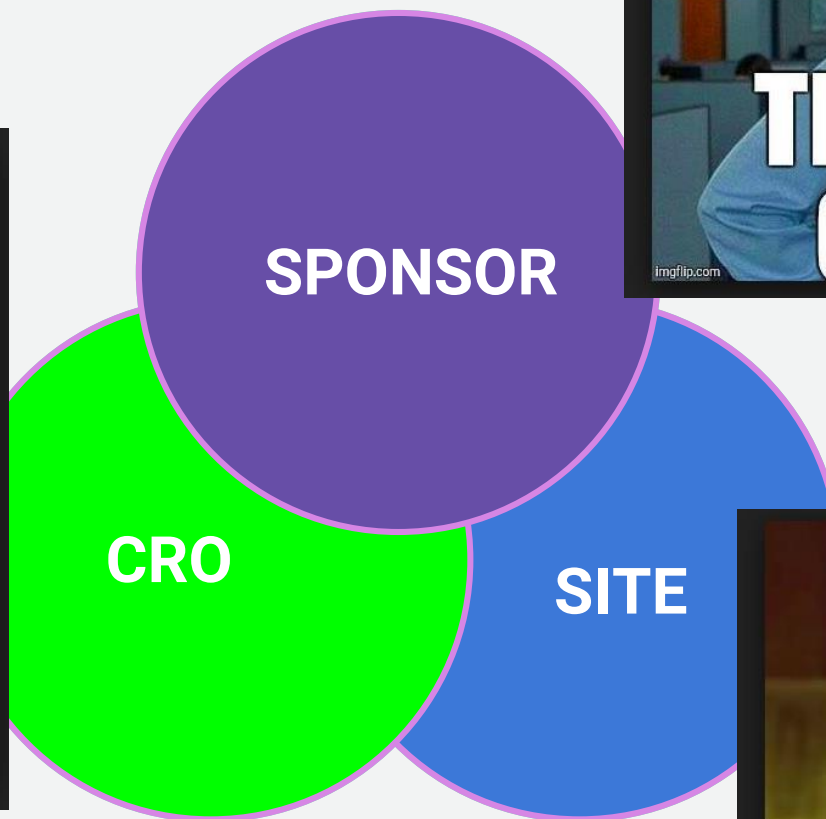
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What sponsors want

Provision of quality data

Enrolling eligible study subjects

Meeting timelines



What sites want

Provision of quality data

Enrolling eligible study subjects

Meeting timelines

Appreciation & recognition

Realistic expectations

Efficient negotiations

Payment schedules

Communications

What sites want

"OK team, if you could say 2 blunt but constructive things, without any comeback, to a bunch of sponsor staff what would they be....."

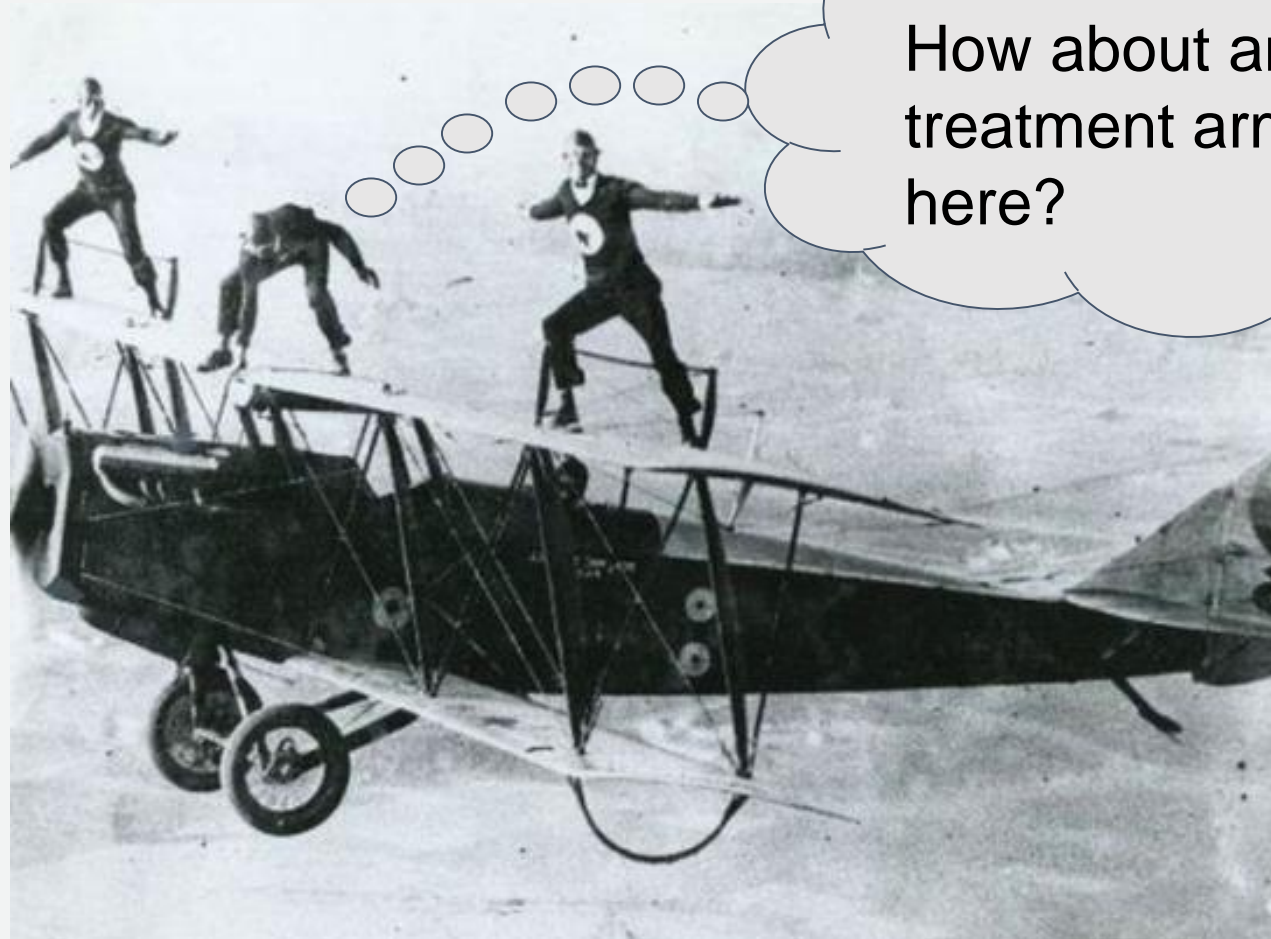


Study Requirements

- ✓ **Contracts**
- ✓ **Regulatory Documents**
- ✓ **Site Initiation Visits**
- ✓ **Source Documents**
- ✓ **Training**
 - Protocol
 - Test Procedures
 - EDC/imaging/medication



Study start up



How about another
treatment arm right
here?

Study start up



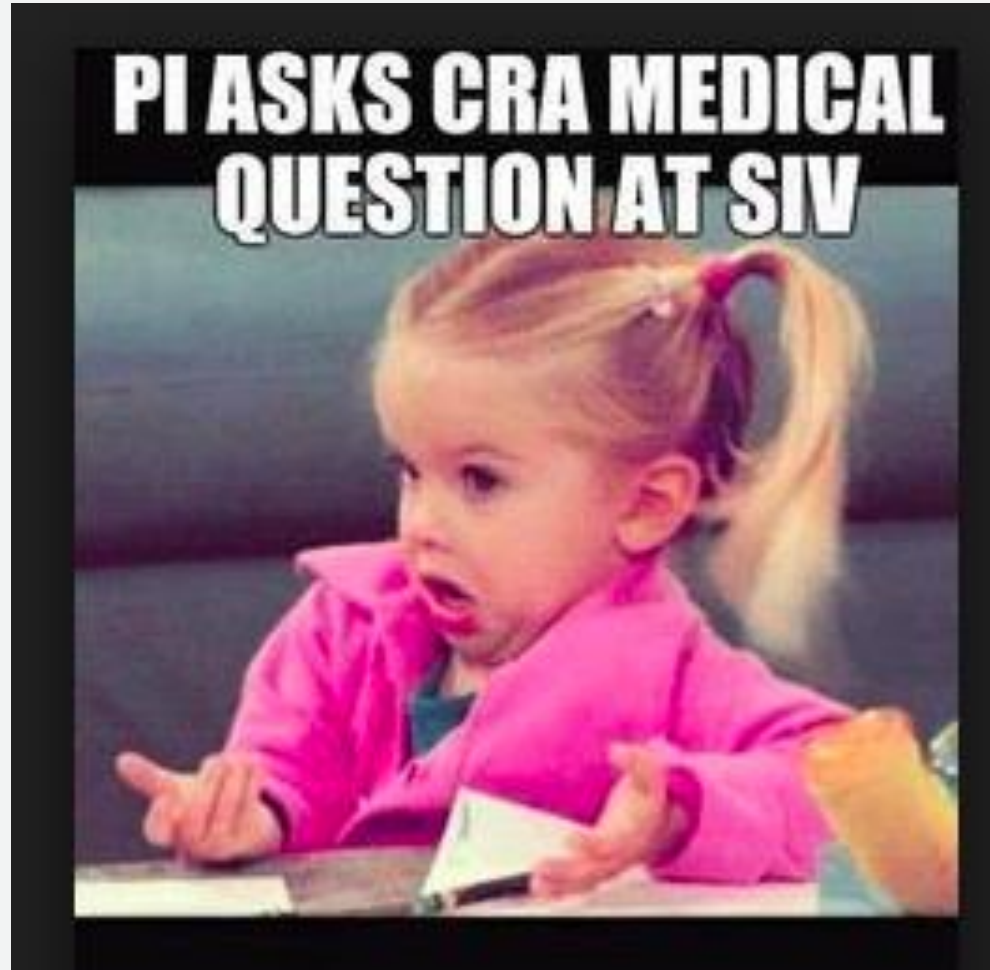
- **Start up timelines: there's an SOP for that**
- **Budget negotiations**
- **Vendors**

After start up

- Know and prepare your monitors
- Read and follow our monitoring SOP
- Offer realistic timelines
- Provide ample opportunities for face-to-face training



After start up



After start up




- Amendment overload
- Remote monitoring
- Well-designed source docs / EDC

After start up



An example

Subject: USA022-002

Page: Sputum Sample Collection - V1 - Screening 

Was a Sputum Sample obtained?

Yes   


If Yes, did the Subject undergo the sputum induction procedure?

No   

If No, please specify reason

If Other, specify

 If No, please specify reason is not other, yet If Other, specify is present, please clarify

Opened To Site from System (08 Feb 2019)



Data Entry Error

PATIENT PRODUCED
AMPLE SPUTUM

Date Sputum Sample obtained (DD/MMM/YYYY)

06/FEB/2019

Assessment of colour:

Mucopurulent (pale yellow/pale green)

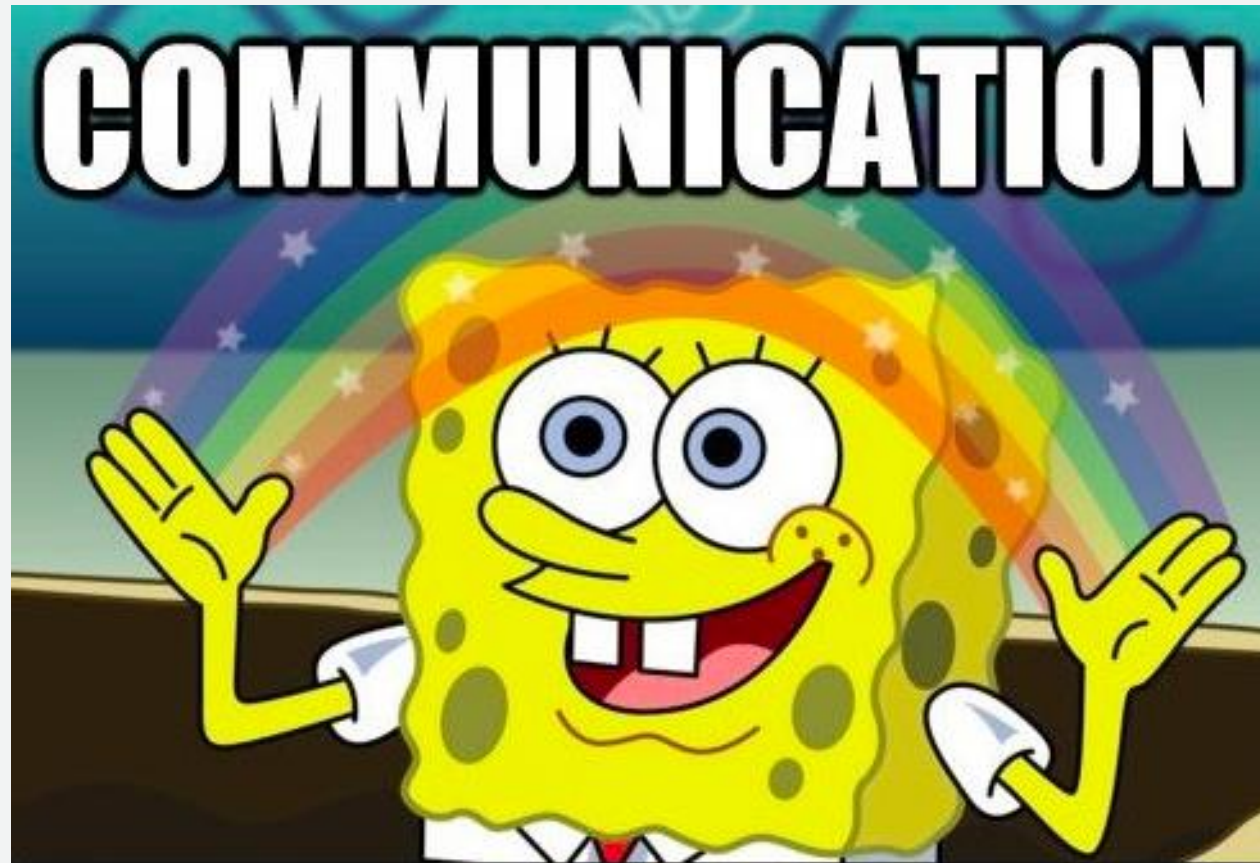
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Save

Cancel

And last, but definitely not least...



Communication



- Stakeholder communication
- Help us stay on top of queries
- Realistic timelines (again)
- Keeping sites “in the loop” with changes
- Email v portal

Final thoughts





Thank You



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