Ongoing challenges from the site's perspective

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Conflict of interest

Honoraria/advisory role:
BMS, MSD, Roche, AstraZeneca, Novartis, GSK, Daiichi Sankyo, Regeneron, Nektar, Pfizer, Janssen, Amgen, Gilead

The site’s and Sponsor’s common goals in clinical trials

- Enroll as much patients in clinical trials as reasonnable
- Put a maximal effort on quality of data

To achieve these goals during our business hours we should be able to concentrate on them

Sounds obvious? Maybe, but…

Clinical trials awareness
our first obstacle

- Patients – we need a positive campaign
  - Without clinical trials progress and new registrations are impossible
  - Clinical trial participation is one of the options of choice in multiple recommendations
  - Patients enrolled can be treated with new technologies
  - In clinical trials patients get „extra care”: coordinators help to navigate in all procedures, travel and meal costs’ reimbursement

- Medical community
  - Referral of my patient proves that I am good enough
  - Referring a patient means less procedures (I am paid for them)
  - Why should I do it?

Clinical trials procedures require additional human resources
second obstacle – too much tasks

<u>Coordinators</u>

Sponsors and CROs trend to delegate more and more administrative tasks to S.C.:

- Endless logs to be filled, scanned, sent
- Monitor kits' and IP stock
- Assemble kits manually
- Send images, drug accontability, PROs, local lab results to systems (3 to 10 platforms in each study)
- Travel reimbursement management etc, etc, etc

A good SC is trained for years – do you really want them to do things that do not lead to quality of data?

Can this all be done by CROs or third parties?

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Investigators

- I receive about 200 e-mails related to clinical trials per day!!!! Some of them need my immediate action and some need to be distributed to my staff. Even if it takes 1 minute per e-mail – about 4 hours of my time is dedicated to e-mails only.
- Please send us one e-mail per project per week – it will spare us hours E-mail should be as short and informative as possible
- PIs need to take care of multiple logistic problems – study drug supplies, rescue medication availability, certificates of everything, PROs availability, travel cost reimbursement (please!)
- Calculation of visits and procedures to be paid

We should concentrate on enrollment stategies, ideal protocol adherence, oversight awesome source data, permanent trining os study team and especially patients's safety

We can improve a lot together

Investigators, study coordinators and the entire team are dedicated to clinical trials

We want to enroll patients and provide sponsors with optimal quality of data

Let us do our job

We want to be delegated to tasks that require our professionalism – that’s why we were invited

We will enroll more patients if our time is not wasted