How to get involved in clinical research

Perspective from the site

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

- Consulting, Speaking honoraria

  BARD, Medtronic, Spectranetics, Biotronik, Bayer Healthcare, Daiichi Sankyo, Intact Vascular, Profusa, Rexgenero,
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I would never be able to give this talk if some things would not have happened!

Quite simply coincidence!

3/2009 Meeting in Milano/Italy

- I was invited to give a talk on behalf of my former boss
- DCB company was looking for EU sites to take part in DCB trials
- Vienna was on the list [prominent researchers, but they were tending to change their working basis into private practice]
- I was introduced and I told them if they’d choose our site, we would be the highest enroller in the trial
- They for sure thought I’m crazy, but they chose our site, because you can always afford one site which is not performing well
- Back home I was confronting my 2 study coordinators at that time with the facts
- The only reason they did not quite right away was the fact that the IV meeting was taking place at Lago Maggiore
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Some 7 years later!

We oversee 50 trials we have been involved since then.

We are usually a high enrolling site.

We love participating in whatever new research area is opened.

We produce high quality.

And we love it and we have fun!
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But it was only coincidence!
And we were not a KEY OPINION Leader at that time!
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How to achieve that!

What’s important for a sponsor when selecting sites?

- High number of patients to be enrolled within the expected time frame
- No false promises
- Sites must stick to their promises and expectations they have aroused
- Good quality [Study procedures, Data acquisition...]
- No issues with regularities and inspections
- Straight forward process with EC, competent authorities and contract issues
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How to achieve that!

How does a sponsor find new sites and what aspects do they look at to select those sites?

That’s the ISSUE!

- Suggestions are made by database of CRO’s
- Suggestions are made according to surveys
- Suggestions are made by personal recommendations

- These are not always reflecting the actual landscape!
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How to achieve that!

Are there specific items, next to the medical components and the specifics of the physician that sponsors look at, e.g. contracting, collaboration with other departments (ER, radiology, ..) relation to the EC, ...?

YES, for sure!

- Contracting should be straight forward and not demanding months [standardized contracts..]
- Collaboration with other departments (ER, radiology.. should be easygoing, straight forward and friction free)
- Relation to EC or other regularities should be easygoing and not demanding months
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How to achieve that!

Can you anticipate specific requirements?

**GCP certificates are a must have! No doubt about that**

- But an issue often is that sponsors do not accept GCP certificates from other trials
- GCP certificates you can acquire from the internet are costly [>70 Euros/each; who is paying???]
- GCP certificates could be acquired through IV meetings and SIV´s.
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How to achieve that!

How do sponsors select the countries?

- Mostly simply convenience
- You know your players! [even if they do not perform well, you are used to it]
- Strategic reasons [you need to invite your key opinion leaders]
- A new country might be an unexplored territory, uncertainty is not something you want for studies
- For registries the reimbursement fact
- CRO related issues:
  - Do you have CRO´s speaking the according native language
  - Locations easy and cheap to reach by the CRO´s
  - A bundle of sites within a country [makes it easier for regularities and all other issues]
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How to achieve that!

How does reimbursement affect the selection of countries/sites?

Affects especially the registries in a real world scenario!

**Real world registries:** Independent form the quality of the sites, if reimbursement is not available you can skip the country/sites

**RCT’s:** No country will show any enthusiastic interest in a RCT with a device or drug if reimbursement might be an issue in the follow up
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Involvement of new players!

Eastern European countries!

- They are clearly underestimated and do not have a voice!
- They are not key opinion leaders in whatever scientific field (only exceptions)
- They are usually very ambitious and try to provide high quality to be respected (maybe they might focus more on quality than other players as that’s the issue they want to be respected on)
- The patients in Eastern European countries are more willing to take part in trials due to their limited treatment options

Most important: They reflect the spirit!
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Involvement of new players!

Eastern European countries!

How to make yourselves as a site known by the sponsors?

- That´s difficult! I do not think that an Italian fountain is there at each please!
- Talk to sponsors, keep talking, make them aware of you
- Attend meetings (find your Italian fountain)
- Talk to the Key Opinion Leaders, they may tell the sponsors
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Involvement of new players!
Eastern European countries!

My expectations to now sites?

- Simply stick to your performance!
  - Enroll as planned
  - Follow up as planned
  - Keep on top of the necessary administration

- I know that a lot of them have a really high spirit for scientific issues!
- So just not downgrade them, upgrade them!
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What’s important for you when participating in trials?

- Quite simply stick to the expectations!
- Provide high quality
- Partners I can reach out/communicate with (Industry/CRO´s, EC, Competent authorities) who do understand and relate to our site´s issues
- Being set up with a study team I can rely on!
- Not being confronted with issues which are unrealistic to reach [eCRF, changing requirements over time during trial..]
- Money we are offered for the study must cover our work!
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How can PI/sites support the overall study set-up and execution at their hospital?

- If they know from the beginning what is the work flow, what they have to solve as crucial issues it is very easy!
- But they must to know it!
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- **To summarize!**

- Being involved in clinical trials is a very much loved but also hard working challenge!
- CRO`s and sponsors make some fatal choices as they do not choose the right sites (sometimes very very superficial views)
- Reaching out to physicians who might not been well-known but ambitious might be the right direction
- Look where the young people are who want to get involved
- Look for quality!
- Look for involvement!
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