Key success factors for good looking data

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Realising the Value from Health Data for Improving Care and Research
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Clinical Research is becoming more complex year by year in all the phases, from the feasibility to the trial closure, for both the sites and the sponsors.
FEASIBILITY EXERCISE

Long questionnaire

Much data requested

Too much information in a very short time
Quite impossible for the investigators to provide a genuine feedback about the protocol (especially inclusion and exclusion criteria) in an early phase.

Confronted with inefficiently designed clinical trials.
Forecasts about the number of eligible patients and the time to completion of trial not correct
Identifying eligible patients more complex than expected

Almost 50% of all trial delays caused by patient recruitment problems

Delay in giving the possibility to the right patients to be treated with innovative and tailored compounds
Very frustrating and discouraging for investigators and sponsors
CHALLENGES FOR SPONSORS IN PERFORMING CLINICAL TRIALS

- High investment of resources in trying to motivate the sites

- Frustration in not reaching the commitment

- Frustration in not having the possibility to treat patients with innovative compounds

- Poor quality
CHALLENGES FOR PATIENTS IN PERFORMING CLINICAL TRIALS

Lose the possibility of receiving a better drug
WHAT CAN WE DO???

How to improve the performance in clinical trials?
WHAT CAN WE DO???

1) What would the sites like to have from the Sponsors?
2) What would the Sponsor like to have from the sites?
POSSIBLE SOLUTIONS

How could technology help us?
POSSIBLE SOLUTIONS

- Electronic Health Record to conduct feasibility in a fast and precise way
- Electronic Tool to find eligible patients in the different departments in a fast way

Reducing time for data analysis
Benefit for patients in having new treatment faster
Reducing cost for drug development
EXPECTED RESULTS

Faster trial activation and conclusion

Less complexity

Less cost and resources

Quality improvement
ACHIEVEMENTS

A single source of data for all systems
We should be ready to be competitive
Anyway, in view of the current context, we must change...

Change is a process...

Current State → Transition → Future State

Not an event.
Thank You!!!