



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 IN ITALY

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



FEASIBILITY EXERCISE

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



FEASIBILITY EXERCISE



Forecasts about the number of eligible patients and the time to completion of trial not correct



ENROLMENT PHASE

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

ENROLMENT PHASE

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?



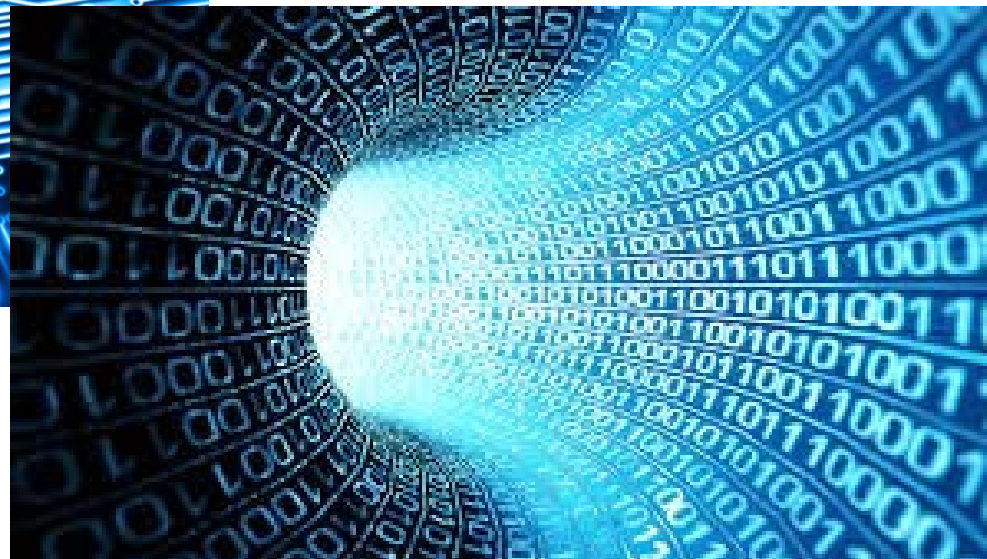
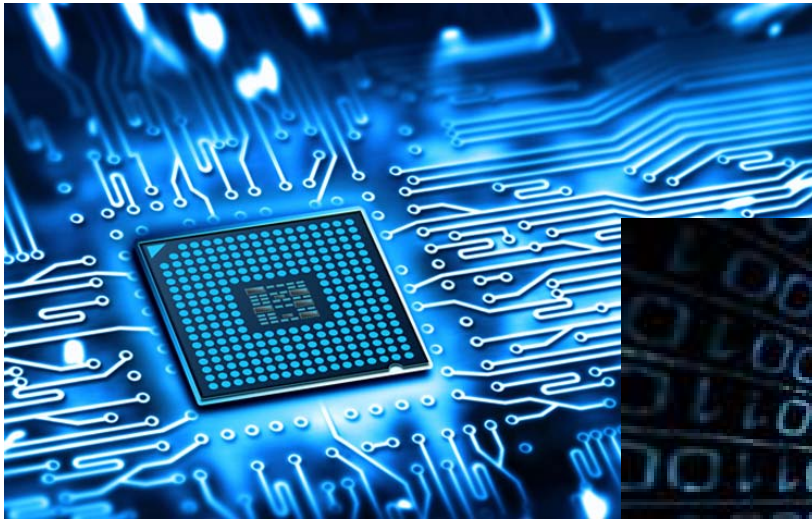
POSSIBLE SOLUTIONS

2) What would the Sponsor like to have from the sites?



POSSIBLE SOLUTIONS

How could technology help us?



POSSIBLE SOLUTIONS

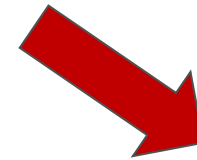
- ✓ **Electronic Health Record to conduct feasibility in a fast and precise way**
- ✓ **Electronic Tool to find eligible patients in the different departments in a fast way**



Reducing time for data analysis



Reducing cost for drug development



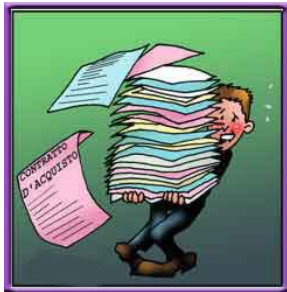
Benefit for patients in having new treatment faster

EXPECTED RESULTS



Faster trial
activation
and
conclusion

Less cost
and
resources



Less complexity

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...





**Thank
You!!!**