Sponsors, CROs, and investigative sites widely agree......

protocol feasibility assessments are frequently exercises in futility

is an international biotechnology and pharmaceutical consulting company, led by senior people who have developed more than 30 products globally from discovery to market. Our Managing Partners personally direct a global network of people that cover a wide range of drug development expertise with skills to operate in all project areas.

Our support is hands-on, not just consulting, which means we don’t just advise you, but we actively implement the strategies and plans that we formulate with you.

Whether you are planning towards your first clinical study to achieve your next inflexion point, or managing complex registration studies, can help you reach your next development milestone.

For more information, visit us at www.cddi.co or contact one of our Managing Partners.

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evidence based protocol feasibility

The Problem
Most patient studies do not complete on schedule.

The Reasons
60% of protocols need amendments and on average there are 2.3 amendments per protocol.
1/3 of amendments are due to protocol description and patient eligibility criteria.
Protocol feasibility questionnaires are ineffective. “Often the best that sites can do is guess, ... their estimates essentially come from gut intuition.”

The Solution
cddi has developed evidence based protocol feasibility, a process that we manage on behalf of our clients that ensures protocols are truly feasible.
We will take your protocol synopsis (prepared with or without our input) and test the “do-ability” based on actual patient records.

The Process
cddi manage a series of steps from synopsis to protocol. We identify and work with investigators at representative sites, gain their support for our process, and collect and analyse patient data.
Inclusion and exclusion criteria are challenged against the evidence from records, answering the question “do the patients exist?”

The Painful Cost
- The average delay to patient studies is 4.6 months.
- Each day of delay may cost $35,000 per day per trial.
- Direct increased costs for additional sites and project management.
- Delay to the drug development programme or publication plan.
- Potential impact on the product’s NPV.

The Benefits and Value
- Protocol feasibility is based on real data not on a ‘guesstimate’.
- Protocol is adapted prior to finalisation, avoiding amendments.
- The number of patients per site is accurately predicted.
- The number of sites needed is optimised.
- Planned dates are met.
- Resource, time and costs are saved.