

PROFESSIONALIZING CLINICAL RESEARCH AT TWO UNIVERSITY HOSPITALS IN BRUSSELS

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INTRODUCTION

Clinical research is going through a new crisis:

- fraud in clinical research worldwide is up – not down – despite a formidable boost in coercive legislation and inspections,
- patient recruitment remains a serious problem despite the globalization of clinical trials because emergent countries have limitations concerning, e.g., medical technology, qualified clinical staff and patient education. Hence, clinical trials, especially in Phases II and III, still rely heavily on hospitals in the advanced economies with highly skilled workers, jammed with technology,
- however, clinicians in western hospitals hate the bureaucracy of clinical trials, and are constantly distracted from clinical research work by all other duties (patient care, teaching, administration of their departments, hiring co-workers, etc.).

Large healthcare institutions need a strong clinical research activity for the following main reasons:

- to participate in the advancement of medicine,
- to offer patients new diagnostic, therapeutic and preventive solutions as early as possible after their discovery,
- to improve the quality of standard of care in general by submitting a large number of staff regularly to the hard discipline of research,
- to educate and train new professionals in the discipline of clinical research.

In the USA, where academic medical centers derive a significant amount of grants annually from clinical research, clinical research activities on campus have been professionalized since the mid-90ies by creating central clinical research offices which assist all investigators of the healthcare institution in the following areas of clinical research:

- business development with sponsors and contract research organizations on behalf of investigators, which includes costing and the development of contracts,
- providing temporary staff from a central pool of study nurses and study coordinators,
- managing the finances of clinical trials in the best interest of all parties inside the institution.

As a result, American sites participate in 60% of all Phase II clinical trials worldwide and in 30% of all Phase III trials.

Since 2004 in the UK, the National Health Service gave certain teaching hospitals the opportunity to create clinical research units. INSERM in France followed suit, and similar schemes have emerged here and there in other Member States of the European Union. Characteristic for all schemes in Europe is the chronic shortage of public funding and the exclusion of most hospitals in the country from the scheme.

We are reporting about a new public-private partnership (PPP) initiative to establish a clinical research unit on the campus of University Hospital Brugmann and Queen Fabiola Children's University Hospital in Brussels in collaboration with Crossover CRI AG in Switzerland, a company which operates clinical research units (CRUs) on behalf of hospitals. We report here some results after 2 years of experimenting with this new model.

METHODOLOGY

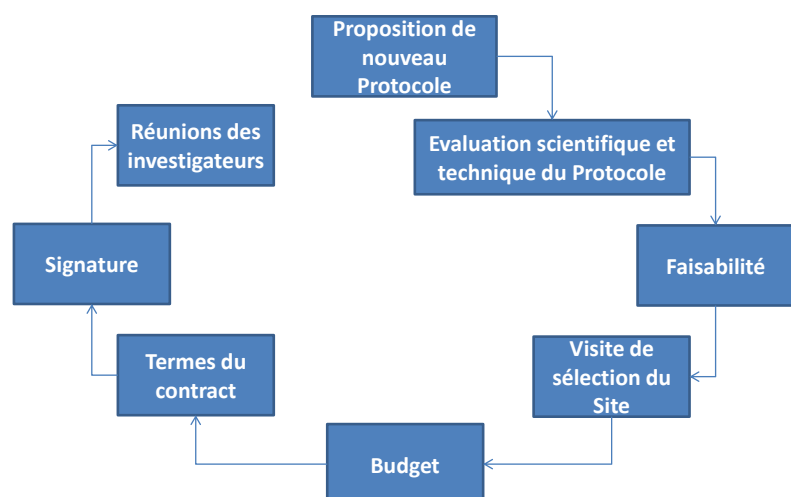
Crossover provides support in managing the following key CR processes inside hospitals.

CLINICAL RESEARCH GOVERNANCE

A Clinical R&D Committee was instituted to discuss clinical research issues on campus at least on a monthly basis. Motivational meetings were organized between the departments and the CRU. The introduction of SOPs, in-depth GCP training and internal audits improved the quality of work delivered to sponsors. There is a masterlist containing all clinical trials on campus. One feature is a patient tracker, which tracks all patient visits. Statistics are produced regularly as well as periodic reports. The CRU ensures a professional input in protocol design and protocol development for non-commercial studies.

FROM FIRST CONTACT WITH THE SPONSOR TO THE CONTRACT

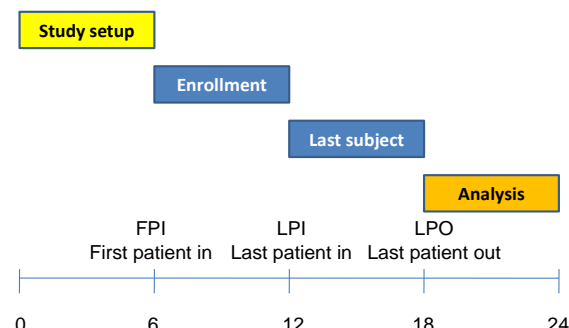
From 1st Contact to Contract



MANAGING THE CLINICAL STUDY

Trial Management Process

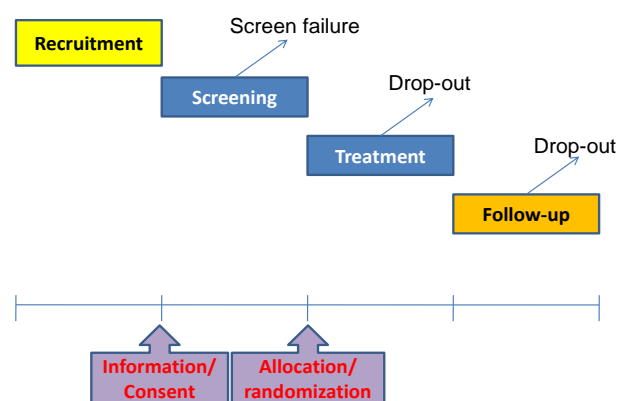
From Study Initiation to final report



MANAGING EACH PATIENT IN THE STUDY

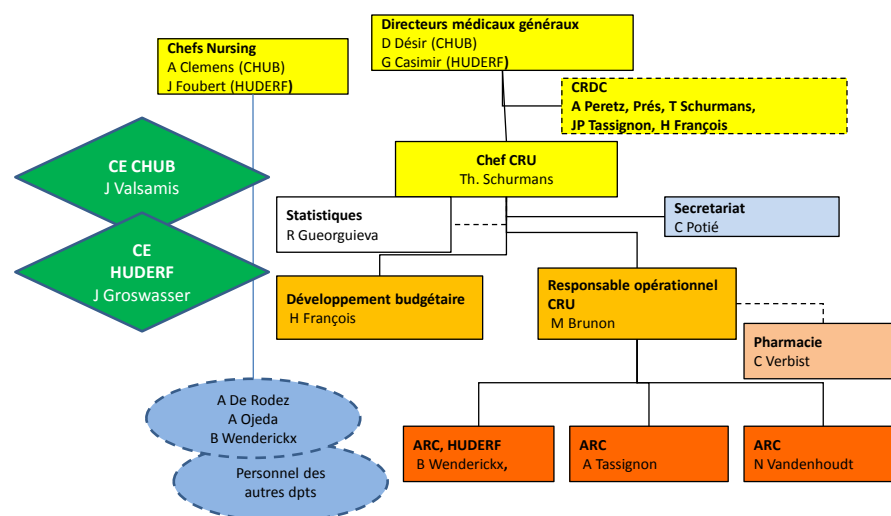
Subject Management Process

From Subject Selection to Discharge



Crossover also brings an investment in infrastructure (freezers, air conditioning, IT, office furniture and equipment, telecom, etc.), matched by the hospitals which provide office space, utilities, cleaning, and ethernet cabling. All partners provide staff (senior management, ethics committee and research nurses for the hospitals, CRU staff for Crossover):

CRU Composition and Environment



RESULTS AND CONCLUSIONS

The hospitals supported by a central CRU had more clinical trials on offer (the number of new proposed protocols increased by 22% in 2009 and again by 24% in 2010). The type of studies shifted towards Phase II and III, without diminishing Phase IV. We were able to set up for the first time Phase I studies in healthy volunteers, with clinical pharmacology endpoints. The clinical study coordinators were asked by one sponsor to monitor the other hospitals in Belgium participating in the same study. The average grant rate improved as we were able to cost clinical trials in a more consistent way.

All efforts are concentrating currently on improving patient recruitment.

From the costing point of view, we are still struggling with the denial of pharmaceutical sponsors about the real costs of well conducted clinical trials to the healthcare institution.