L-Università ta' Malta
Faculty of Medicine & Surgery
Department of Pharmacy

Inter-Professional Collaboration in Clinical Trials

Anthony Serracino-Inglott, Janis Vella Szijj, John J. Borg*, Lilian M. Azzopardi

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

*Malta Medicines Authority, Life Sciences Park, Malta

email: anthony.serracino-inglott@um.edu.mt

INTRODUCTION

The granting of a marketing authorisation for a medicinal product relies on a pharmaceutical regulatory process that includes the submission and elaboration of a well-planned, organised clinical trial. Within the clinical trial procedure, aspects of quality, safety and efficacy of the medicinal product under review are assessed. The successful planning and elaboration of clinical trials relies on effective interprofessional collaboration.

AIM

To identify the role and function of interprofessional collaboration from the time of the initial planning of the clinical trial, to the execution and submission of the report to the medicines regulatory authorities.

METHOD

- **Steps involved in the development of clinical trials are characterised by evaluating case studies and reviewing experiences from pharmaceutical regulators and investigators.**
- **Stakeholders involved in the planning and execution of clinical trial process are identified.**
- **Opportunities for interprofessional collaboration are highlighted**

RESULTS

The key players of the inter-professional team were identified (Table 1). For the interprofessional relations to be successful, work practices which were identified were: identification of milestones, pre-submission meetings, interim reporting with data access, transperancy amongst all parties, effective communication whilst avoiding overburdening the communication channel and presentation of immature results.

Table 1: Key players identified

Position	Responsibilities
Project Manager	facilitate interprofessional dialogue
Qualified Person	release investigational medicinal product from the manufacturing
Ethics-Data Officer	follow-up ethics committee requirements, consenting of human participants
Clinical team lead	oversight and co-ordination of the clinical professional contribution
Clinical site representative	prepare approvals and provide logistic requirements
Clinical trial dossier rapporteur	compile documentation required for submission to sponsor
Finance and agreements liaison officer	establish the collaborative framework amongst the parties

CONCLUSION

The undertaking of a clinical trial is a milestone for the pharmaceutical research and development department of pharmaceutical companies and is an opportunity for clinical investigators to contribute to safe, effective and quality innovation in the pharmaceutical aspect. To ensure that the resources invested towards clinical trials is effective and contributing to safe and accessible innovative medicinal products, it is crucial for the trials to be undertaken in a robust and resilient manner. Identifying role and function of interprofessional collaboration within the planning and elaboration of clinical trials supports the robustness, resilience and efficiency of the process. The results presented identified interprofessional practices that are necessary and which are often underestimated in real-case scenarios.