Singapore Healthcare Management 2019

Harmonising Requirements for Research e-Documentation in SCM

Jasmine Foo | Fayth Tan | Sue Tee
Clinical Trials Coordinating Centre (CTCC)
SingHealth

INTRODUCTION

At SingHealth, patients' electronic medical records (EMR) are maintained by the Sunrise Clinical Manager (SCM) system. This poster describes the project undertaken to harmonise the requirements for integrating research documentation into the SCM cluster-wide.

OBJECTIVES

- Ensure patient safety
- Compliance with regulatory requirements of the Health Products Act (Clinical Trials) and Human Biomedical Research Act

CHALLENGES

>1200 Users in Research

Varied requirements from multiple user groups e.g. Investigators, Clinical Research Coordinators, Allied Health Professionals

3000 On-going Research studies

Consolidation of different study specifications from 5 types of nature of study in more than 30 therapeutic areas

6 Key Considerations

- Patient safety
- Regulatory requirements
- System capability
- Stakeholders' buy-in
- Data confidentiality
- User experience

METHODOLOGY

Jan 2018 → Sep 2018 → Now

- Formation of eClinDoc Research Workgroup, represented by each institution
- Discussions through 5 workgroup meetings and 2 voting sessions
- Prototype of SCM research document template developed by IHiS
- 2 committee presentations and incorporated stakeholders' feedback
- Finalised 'CTR Research Note' template presented for approval

RESULTS & CONCLUSION

IHiS developed the document template for research in SCM '**CTR Research Note**', based on the consensus of the eClinDoc Research Workgroup and in consultation with Group Medical Informatics.

The template was designed to comprise essential information required by regulations and is organised into 4 tabs; Research Note, Informed Consent, Communication Log for (Serious) Adverse Events and Investigational Product.

'**CTR Research Note**' is currently being reviewed by SingHealth Senior Management for approval and implementation cluster-wide.