Project Title

JESSED – an in-house clinical trials management system

Project Lead and Members

Project lead: Beh Wei Heng Edward

Project members:

- Wang Jin, Senior Manager, Clinical Trials& Research Centre (CTRC)
- A/Prof Koh Siyue Mariko, Director, Clinical Trials& Research Centre; Senior Consultant, Dept of Respiratory & CCM
- SGH CTRC Clinical Trial Coordinators and Administrators

Organisation(s) Involved

Singapore General Hospital

Project Period

Start date: 2018

Completed date: On-going

Aims

To capture the performance of CTRC accurately, efficiently and in a timely manner

Background

The Joint Excel Study Status Electronic Dashboard (JESSED) project was conceptualized and started in Clinical Trials and Research Centre (CTRC), Singapore General Hospital (SGH).

SGH CTRC is the main trial coordination centre in SGH. CTRC typically manages > 60 clinical trials (CT) per year and has > 10-14 different coordinators in charge of various trials at any given time. Before JESSED was created, study status data were collected using pen and paper and manually entered into an Excel database by admin staff periodically.

Clinical trial performance, recruitment status, adverse event reports, protocol deviations, financial data were not captured systematically.

The old process was labour-intensive, prone to human error and not easily analysable. Data collected are either incomplete or inaccurate due to change of manpower over the years.

Management of CTRC did not have real-time update of the centre's overall performance (e.g. operational, financial, safety and quality) and could not view trends in performance and demand.

Methods

See attachment

Results

See attachment

Lessons Learnt

- A system customised to the needs of the users is far better than any commercial system. Our system is built from bottom- up approach, taking the feedback of the users (coordinators, administrators, PIs, research office) right from the beginning. Therefore, the end-product is readily-adopted, scalable, and remains relevant despite unforeseeable circumstances (e.g. cyber-attack on Singhealth in 2018).
- Early involvement with IHIS, with their inputs may help the expansion of system.
- Building customized, useful applications from the ground-up is possible even with no funding as long as the right tools are used. Do not give up!
- This application has the potential to transform the way clinical trial centres handle their trials. The workflow streamlined by the application is applicable to all trial centres in Singapore healthcare system, which can save a lot of manual work and help end users focus on their mission to provide better care for the clinical trial patients.

Conclusion

See attachment

Project Category

Automation, IT & Robotics

Additional Information

This project is related to The JESSED Project from the Singapore Healthcare Management (SHM) Conference 2018.

Keywords

Automation, IT & Robotics, Research, Workflow Improvement, Clinical Trials Management, Information Management, Data Collection, Human Error, Clinical Research Office, Singapore General Hospital, Clinical Trials and Research Centre, Electronic Dashboard, Joint Excel Study Status Electronic Dashboard, JESSED

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JESSED:
Joint Excel Study Status Electronic Dashboard
An In-house Clinical Trials Management System

Beh Wei Heng Edward, Wang Jin, Koh Siyue Mariko – Clinical Trials and Research Centre, SGH

Background

1. SGH CTRC typically manages **> 60 clinical trials (CT)** per year and **has > 10-14 clinical research coordinators** (CRCs).
2. Before 2018, study status **data** were collected using **pen and paper** and manually entered into an Excel database by admin staff.
3. The old process was **labor-intensive**, prone to **human error** and **not easily analyzable**.
4. A **lack of real-time** data and information about trend of the centre's overall performance (e.g. operational, financial, safety and quality) was an impediment to the centre's strategic planning.

Assessment and analysis of problem

1. **Meetings were held and feedback gathered** from CTRC CRCs, Admin staff, PIs, research office, sponsors, CROs and other relevant parties about the problems and issues faced.
2. A **lack of a centralized system** was identified as the main problem.
3. Key considerations for an **ideal** centralized trial management system were
   - **Efficiency**
   - **Data Security**
   - **Cost-effectiveness**

3. A commercial system costs at least SGD 500k and **budget was not available**.

Aim

1. To capture the performance of CTRC **accurately**, **efficiently** and in a **timely manner**.
2. A system to **analyze** operational, financial, safety and quality data as well as trends.
3. A dashboard to **visualize** and report data by categories.
4. Ability to filter data quickly for effective, **data-driven decision making**.
5. To achieve objectives above with **secure data storage** in the intranet.

Methodology

1. We **brainstormed** for a solution and decided on an Excel-based application. A **prototype** was built validate its usefulness.
2. With the prototype, we were able to **visualize** data using the existing data sets and spot trends.
3. The prototype was presented to relevant parties for their **feedback** and **modifications** before being developed into a **full-fledged application**.

Measurement of Improvement

The effect of change is measured by the feedback provided by the following user groups:

User Group	Result and Feedback
Coordinators	↓ 50% **reduced data submission time** ↑ 100% **more data points** submitted per month
Administrators	↓ 80% **reduced transcription and consolidation time**
Managers	The application keeps managers **up-to-date** with development of clinical trials under their care. It also enabled them to **visualize trends** and **filter data** efficiently for **data-driven decision making**.

Results

1. In 2018, the **Joint Excel Study Status Electronic Dashboard (JESSED)** was created.
2. JESSED CTMS has since become the **standard** trials management tool used in CTRC and **several other departments**.
3. Coordinators and administrators **spend lesser time** entering and managing data.
4. Trial coordinators and managers have a **more accurate** picture of the trials under their care, including serious adverse events and protocol deviations that may have serious impact on **patients' safety and research quality**.
5. At **no cost** to hospital.

SCAN FOR MORE INFO

JESSED

Conclusion

A system **customized to the needs** of the users is better than any commercial system. Our system is built from **bottom-up approach**, taking the feedback of the users (coordinators, administrators, PIs, research office) right from the beginning. Therefore, the end-product is **readily-adopted , scalable, and remains relevant** despite unforeseeable circumstances. For example, following the recent **COVID-19 outbreak**, we were able to **quickly filter** life-saving trials for contingency planning.