SaTH Pharmacy Improving Amendment Implementation

Theme | Pharmacy Clinical Trials

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REASON WHY?

An amendment is any change to a research project after approval from a regulatory review body has been given. Pharmacy need to ensure amendments are implemented in line with sponsors requirements and any issues/concerns raised with Research and Innovation. There was no standard process for the reviewing and implementation of amendments and no clarity of job roles within the pharmacy clinical trials team resulting in duplication or omission of the work required.

SMART AIM

S SPECIFIC | M MEASUREABLE | A ACHIEVABLE | R RELEVANT | T TIME-BOUND

To improve the process for reviewing and implementing amendments within pharmacy supported research projects by September 2023 as evidenced by percentage performance and adherence to Sponsor agreed timelines.

PLAN

A team was put together in January 2023 to review the regional workflow and streamline the amendment process at SaTH, Key concepts were required to be kept but rationalised to meet Pharmacy needs.

The team comprised all members of the Pharmacy Lead Clinical Trial Team and the Research Governance and Quality Assurance Leads.

edge

DO

The team met and through a series of meetings reviewed the amendment process and the EDGE workflow and made the necessary changes to streamline the process.

Responsibility for each part of the amendment review and implementation process was discussed and clarified.

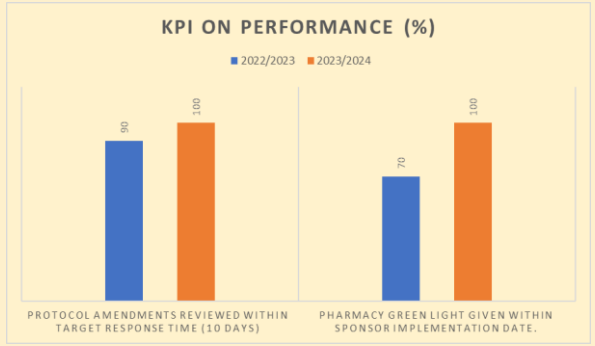
Moving forward the Clinical trial technician leads on all reviewing and implementing amendments including the pharmacist only when required for a clinical review.

Target times for amendments were set to provide meaningful **key performance indicator data**. (KPI)

Standard operating procedures were reviewed, updated and issued to the Pharmacy Lead Clinical Trials Team

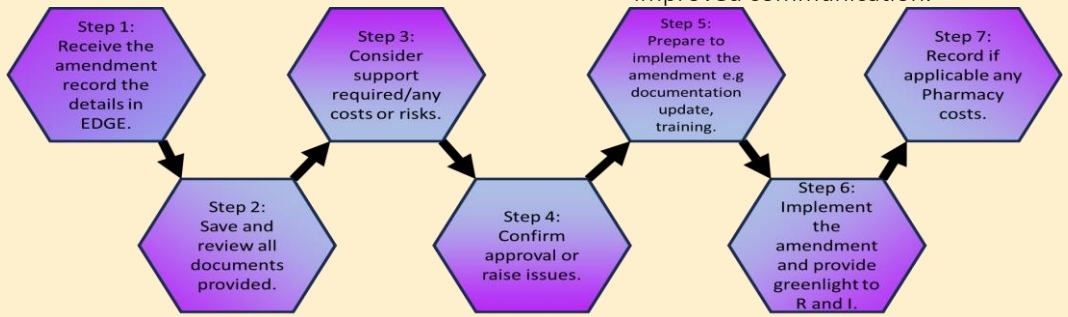
STUDY - OUTCOME

The KPI data demonstrates that pharmacy target times have been met since April 2023 with the introduction of the updated workflow and pharmacy team responsibility review.



The new process has

- Increased response time for processing amendments.
- Fully maximised pharmacy resource – saved time for pharmacists to concentrate on more complex issues.
- Ensured efficient use of workforce skills.
- Ensured no loss of income for Pharmacy.
- More integrated working process with Research and Innovation.
- Improved communication.



ACT

The team will **ADOPT** the review group and continue to meet.

Next Steps

The review group will move on and review the other workflows currently used on site to see if they require updates or changes.

- SaTH Pharmacy EOI/Feasibility Workflow
- SaTH Pharmacy Site File Audit
- SaTH Pharmacy Site File Closure
- SaTH Pharmacy Site File archive.

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