TRUST POLICY AND PROCEDURES FOR THE MANAGEMENT OF SAFETY ALERTS

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	V1	Dec 2007	Kay Fawcett	Original Policy
	V2	January 2011	B.J. Youson	Policy Reformatted to NHSLA Standard
	V3	July 2014	L Fryatt	Updated in line with NHS England Patient Safety Alerting System and organisational changes.
	V4	Nov 2016	Mark Cannell	Updated to reflect Scan4Safety procedures
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To be read in conjunction with: Trust Policy & Procedures for Incident Reporting, Analysing, Investigating and Learning and Trust Policy for the Assessment and Management of Risk.				
In consultation with and Date Patient Safety Committee, Medical Devices Committee Leads, Medicines Safety representatives				
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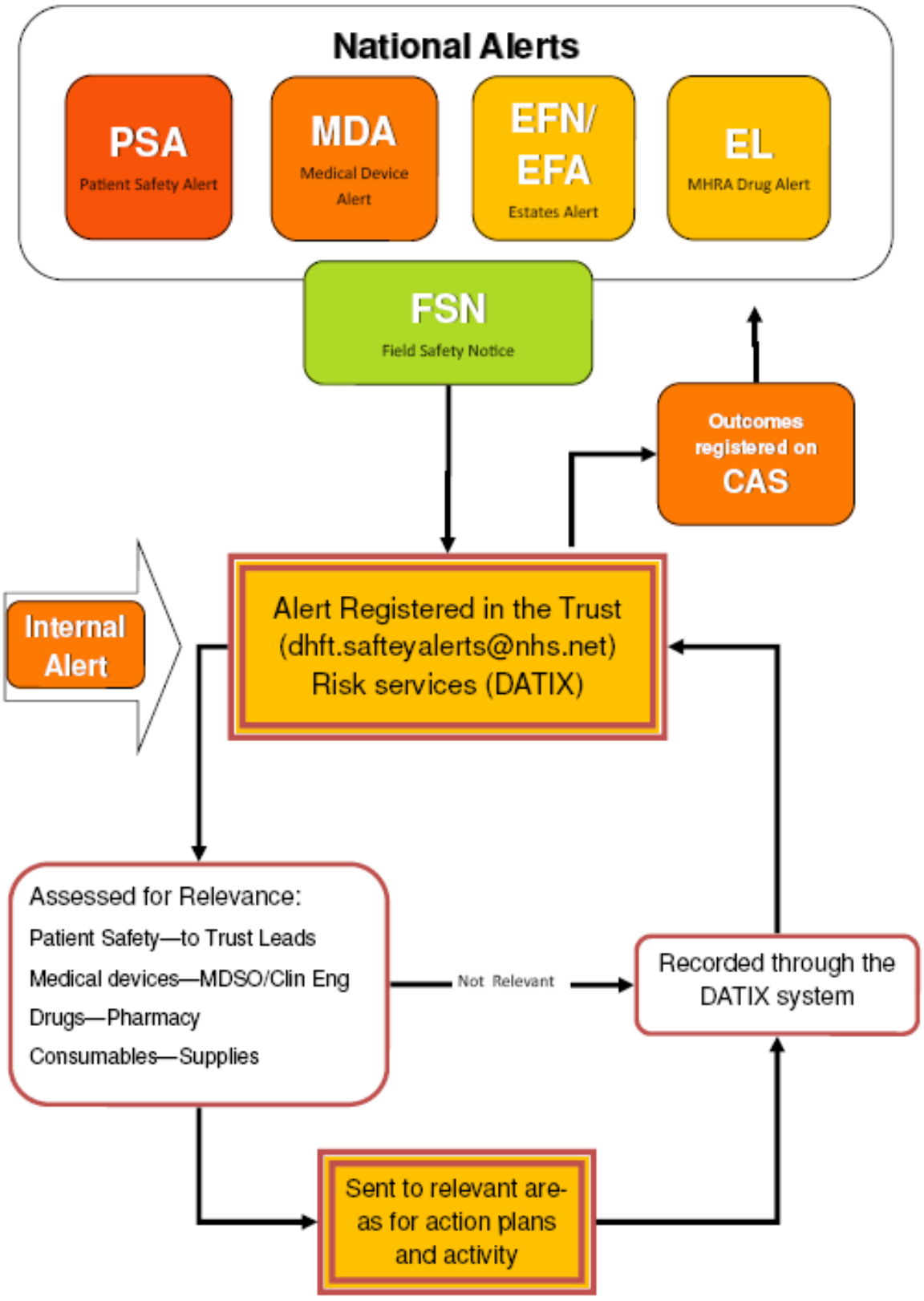
Contact for Review	Clinical Leads for Risk and Governance (Joint between risk lead and medical devices lead)
Executive Lead Signature	Executive Medical Director
Approving Executive Signature	Executive Medical Director

Contents

Simplified General Flowchart



TRUST POLICY AND PROCEDURES FOR THE MANAGEMENT OF SAFETY ALERTS

1. Introduction

It is the aim of the Trust to ensure that all alerts are communicated promptly to all relevant members of staff employed within the Trust, so that relevant actions can be promptly initiated in order to safeguard patients, visitors, and staff from harm. This needs governance to ensure a coordinated approach is maintained such that these responses are measured, effective and evaluated.

As of 1 April 2016, Patient Safety is now part of NHS Improvement, and as such the Patient Safety Alerts are now issued and are published on the NHS Improvement website.

Patient safety alerts are a crucial to rapidly alerting the healthcare system to risks and provide guidance on preventing potential incidents that may lead to harm or death. These incidents are identified using the National reporting systems, these use the wealth of data available to spot emerging patterns, so that appropriate guidance can be developed and issued to protect patients from harm.

These alerts are managed via the Central Alerting System (CAS), a web-based cascading system for issuing/coordinating alerts, important public health messages and other safety critical information and guidance to the NHS and social care (including other organisations and independent providers of health).

The new system retains the process of providing urgent information to healthcare providers via CAS, and the utilisation of the three-stage alerting system, which encourages information sharing between organisations so that examples of best practice can be widely adopted.

In general, each alert is owned and developed by the most relevant of the six NHS England Patient Safety Expert Groups (PSEGs). These are made up of core multi-professionals, including representation from relevant colleges and associations, patient and carer groups, NHS England and Clinical Commissioning Groups (CCG). Wider membership for individual groups includes relevant organisations in a position to promote learning and provide data on patient safety priorities.

NHS England publish monthly data on their website for any Trusts who fail to declare compliance with any stages of the NPSAS alerts by their set due date. Failure to comply is likely to be used by the Care Quality Commission in their Intelligent Monitoring System and as an integral part of commissioners' responsibilities for improving quality. Failure to comply with a Stage Three Alert: Directive within the deadline in particular will be a cause for significant concern on the part of regulators, commissioners and most importantly, patients.

Locally the alerts are managed through the Trusts Risk Department using response tracking and the network of Risk links throughout the Trust to ensure the information is effectively communicated and actions coordinated, this department is also responsible for recording the acknowledgements and outcomes on CAS. To further add a degree of granularity and security to our processes the introduction of the Scan4Safety project adds a system that will facilitate the immediate identification of where a product* is, and if/which patient a product has been used on.

*initially this will be applicable to 'relevant' consumable products as defined by the project.

2. Purpose and Outcomes

The policy applies to all members of staff employed within the Trust who are involved in any aspect of alert dissemination, action, and /or review. The Trust shall provide adequate management of external safety advice to ensure that:

- Responsibility and accountability for the receipt, recording, dissemination and follow-up of safety information is sufficiently explicit
- All Divisions, Business Units, Departments and Staff are made aware of safety information that may be relevant to their areas of work and responsibility
- The organisation responds appropriately and records evidence of its responses to external safety information on how the alerts have been implemented as well as provide details of any remedial actions taken / planned along with timescales for completion.
- Process for monitoring compliance with the above.

3. Alert Definitions Used

CAS	The **Central Alerting System** is a Department of Health web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care (https://www.cas.dh.gov.uk/Home.aspx)
Drug Alert (EL)	Drug Alerts (with an EL prefix) are specific drug based issues, Drug Safety updates are also issued.
PSA	**Patient Safety Alerts**, specific alerts issued in response to incident analysis, now issued by NHSi in one of three forms: *Stage One Alert: Warning. This will 'warn' organisations of emerging risk* *Stage Two Alert: Resource. This may be issued some weeks or months after the stage one alert for the provision of resources, tools and learning materials to help mitigate risk identified in stage one* *Stage Three Alert: Directive. At this stage organisations are required to confirm they have implemented specific solutions or actions to mitigate the risk*
MDA	**Medical Devices Alert**, specific alerts relating to medical devices issued by the MHRA
MHRA	The **Medicines and Healthcare products Regulatory Agency** is responsible for the regulation of medicines and medical devices and equipment used in healthcare and the investigation of harmful incidents. The MHRA also looks after blood and blood products in the UK.
FSN	**Field Safety Notices** are product recall notices that are sent directly

	from the supplier to the Trust.
EFN	**Estates and Facilities Notification** via the Department of Health
HPA (now part of Public Health England)	**Health Protection Agency** co-ordinates health protection across the whole of the UK and is the UK portal for the European Union Early Warnings and Alerts and for Assistance Calls. Many specialist microbiological services are provided at the Centre for the whole of the UK and this helps to ensure consistent UK surveillance data are available for many diseases.
Chief Medical Officer Messaging	CEM/CMO Messages are recorded on CAS as a receipt management process.
LRI	Some of the Trust's drugs are distributed by the **Leicester Royal Infirmary**. In the event of a drug recall, the LRI will cascade the alert to the Trust.

4. Key Responsibilities/Duties

Director of Patient Experience and Chief Nurse

The Director of Patient Experience and Chief Nurse is the Trust Lead for Risk Management and the nominated Executive Lead for CAS at Derby Teaching Hospitals NHS Foundation Trust; and responsible for communicating risk, and safety concerns to the Trust Board.

Head of Patient Safety

The Head of Patient Safety has a linked role to the governance of any actions required should these be relevant to the Trust.

Clinical Leads for Risk and Governance

These are responsible for managing the CAS process within Risk Services, and provide appropriate assurance reports to the Patient Safety Committee and Medical Devices Committees, as per the monitoring matrix. Will risk assess the implication, if action is delayed or a response outstanding; and to inform the escalation process.

Patient Safety Officer

The Patient Safety Officer is responsible (in the first instance) for monitoring compliance with the actions/responses required.

Safety Alerts Liaison Officer (SALO)

The nominated administrator within Risk Services who is responsible for:

- Receiving and acknowledging receipt of CAS notices
- Registering and Maintaining a comprehensive database of alerts received and actions taken the (Currently DATIX)
- Publishing onto the Patient Safety pages on the intranet.

- Liaising with departments e.g. Supplies, Facilities Management, Estates and Clinical Engineering to see if equipment is used within the Trust and the Medical Director for Dear Dr letters and Chief Medical Officer Alerts. Within 2 working days of receipt of the alert.
- Notifying identified Division/Business Unit contacts of Alerts and/or to the allocated lead, for receipt or completion of an action plan (as appropriate to the Alert).
- Chasing responses from the identified Division/Business Unit as necessary
- Updating the CAS web site to state either that action is underway; or that no action is necessary with appropriate reasons for this
- Updating the CAS website when all action has been taken and the matter is resolved
- In conjunction with Clinical Lead Risk and governance collate assurance reports to Patient Safety Committee as per group monitoring matrix

Supplies and E-Procurement Team

It is the responsibility of the Supplies E-Procurement Team to receive the alerts relevant to products (ensuring the SALO is aware) and check on hTrak to see if the product has been used in the Trust or where it is currently located. This will then be reported back to the SALO via DATIX.

Pharmacy Logistics Manager

The Pharmacy Logistics Manager, or Deputy, with the assistance of the Medicines Information Pharmacist (where needed) manage the process as outlined in Pharmacy Services Procedure for the Handling of MHRA Drug Alerts.

Division / Business Unit Coordinator

Each division/business unit shall nominate an appropriate individual (Appendix 4) responsible for local dissemination of the Alert; and collating the responses and action plans, and responding centrally to Risk Services (Via DATIX). Where they shall maintain documented evidence of action taken; discuss safety alerts which appear highly significant in their area at the local Division / Business Unit Risk / Governance Group and, ensure a risk analysis is undertaken where appropriate.

All staff given an alert for action

Will take appropriate action for safety alerts and report back to the Division / Business Unit Coordinator. Advising their managers (Via DATIX) where action is required beyond their sphere of control.

Patient Safety Committee

This committee will receive reports from the Clinical Lead for Risk and Governance on a monthly basis to provide assurance to the Quality Review Committee (QRC) and ultimately Trust Board of compliance with the alerts.

Issues of non-compliance will be addressed through this committee and will be escalated to the QRC as appropriate.

Medical Devices Committee

This committee has responsibility for the effective use and purchasing of Medical Equipment for the Trust, as part of its remit of managing these also requires assurance of compliance with relevant Alerts.

5. Implementing the Policy and Procedures

Receipt of Alerts

Alerts are sent to the Safety Alerts mailbox. The SALO will acknowledge receipt to CAS within 2 working days. In times of the SALO being absent, access to the e-mail address box will be assigned to another member of the Risk Management Team.

The SALO in conjunction with the Patient Safety Officer will undertake an initial review to determine which staff should be involved with taking actions in respect of the alert. This will usually involve communication with the Procurement Manager, Equipment Library Manager, Facilities Management or Pharmacy Manager to confirm whether or not products affected by alerts are in use within the Trust. The following table details the initial review process and subsequent action for each type of alert.

Internal Alerts

In addition to the CAS alerts this procedure also allows for the generation of Internal Trust alerts that may need to be issued by the Trust to provide rapid and effective distribution of information, e.g. following a Serious Incident (SI), incident or accident.

The distribution process will follow the CAS procedure with the exception that progress of actions will not be reported to the Department of Health. An internal alert will only be distributed following the agreement of the Director of Patient Experience and Chief Nurse and/or the Medical Director.

Dissemination of the Alert

The SALO will review the content of the alert and seek advice from the Clinical Lead Risk and Governance or nominated deputy to decide if the alert is relevant to the Trust. Assisting this decision will be checking on the hTrak system (dhft.Supplies@nhs.net) or Clinical Engineering systems (AIMs) (Appendix 4).

Once identified that the product alert is relevant, the actions required as identified on the alert will be followed and this will be communicated out to the relevant areas of the Trust.

The correspondence includes the Safety Alert, any additional information provided by the Central Alerting System and, where applicable, a response sheet or action plan to be returned to the SALO (Appendix 5) detailing Division/business unit action.

These responses / action plans will be reviewed by the Patient Safety Committee at the monthly meeting or virtually if timescales does not allow.

The SALO maintains the CAS safety alerts database; recording distribution, deadlines for action and actions taken, and reports compliance using the following Central Alerting System definitions for returns:

- Assessing relevance
- Action not yet started

- Action Required
- Action Complete

If the alert is not relevant to the Trust the SALO will make a record to this effect on the CAS web site.

Division / Business Unit Action

It is a fundamental facet of this procedure that the Division / Business Unit coordinators ensure that they have a robust system in place to action all CAS notices in a timely manner, including arranging for a prompt, consolidated reply to the SALO; and arrangements for cover for periods of absence. Division/Business Unit coordinators should note the response timescales on individual Alerts and ensure that actions taken are commensurate with the timeframe specified.

Whilst the whole process may be carried out electronically, the Division/Business Unit contacts should ensure that they keep a copy of the alert and responses within their files.

Follow-Up Procedures

The SALO will maintain an information system, which highlights the pattern of responses, in order to verify the efficacy of the system and assist in the reminder processes. In the event that any Division/Business Unit coordinators or other addressee fails to reply to the covering letter / email, which accompanies the CAS Alert, the SALO will send a reminder to the Division/Business Unit coordinators to ensure the new timescales for responses are met and will escalate to Divisional Directors and the Patient Safety Committee any issues/concerns.

An alert can only be recommended for closure once **ALL** returns have been received and the action taken fulfils the terms and wording of the alert. Once the action taken is agreed as sufficient to close the alert this will be signed off by Clinical Lead for Risk and Governance and the SALO will sign off on the National CAS database.

The Clinical Lead for Risk and Governance will ensure that any safety alerts which give rise to any delay in implementation are risk assessed and placed on the Trust or relevant Division/Business Unit Risk Register and escalated in a monthly report to Patient Safety Committee.

Any alerts that are met in terms of action taken but have an ongoing implementation e.g. annual maintenance, regular checks etc. these will be added to an ongoing monitoring log which will be considered by PSC. In monitoring the log the PSC will be seeking the necessary assurances from the appropriate Clinical Governance Facilitators for the relevant Business Units that ongoing actions are being adhered to.

6. Monitoring Compliance and Effectiveness

The key requirements will be monitored in a composite report presented on the Trusts Monitoring Report Template:

Monitoring Requirement :	The Trust can demonstrate compliance in relation to responding to the Department of Health and NHS England within appropriate timeframes
Monitoring Method:	To analyse CAS information system on a monthly basis. A monthly exception report of overdue reports are submitted to the Patient Safety Committee Action plans submitted and agreed and thereafter exception reports.
Report Prepared by:	Clinical Lead Risk and Governance.
Monitoring Report presented to:	Patient Safety Committee who will report any exceptions to the Quality Review Committee.
Frequency of Report	Monthly.

7. References

MHRA (2006) MDA/2006/001 'Reporting Adverse Incidents and Disseminating Medical Device Alerts'. Department of Health

MHRA (2011) MDA/2011/001 All medical devices. Department of Health

NHS England (2014) an introduction to the NHS England national Patient safety Alerting System

Appendix 1 Types of Alerts

Central Alert System
The Central Alerting System currently operates Monday – Friday, 0900 – 1700 hours, excluding Bank Holidays. Alerts are sent out under the following categories:

1.1 MHRA

Immediate Action:
Used in cases of actual death or serious injury, or where death or serious injury would have occurred but for fortuitous circumstances or the timely intervention of healthcare professional (or carer); and where the Trust is expected to take immediate action on the advice.

Action:
Used where the Trust is expected to take action against a deadline, on the advice, where it is necessary to repeat warnings on long-standing problems or to support or follow-up manufacturers' modifications

Update:
Used when the MHRA wish to update the Trust about previously reported incidents or series of incidents, possibly on a topical or device group basis, and where further follow-up safety information is judged to be beneficial.

Information Request:
Used to alert users about a specific issue that may become a problem and where the MHRA are requesting feedback. These alerts will be sent out with additional questions to be completed.

1.2 PSA Alerts:
The Patient Safety Alerts system distributes Patient Safety Alerts which request that each Trust implement the guidance contained within a specified time frame. They also disseminate Rapid Response Reports which allow the various Governing Bodies to identify and respond more quickly to risks and problems that could be widespread. Disseminated as one of three types of alert:

Stage One Alert: Warning. This will 'warn' organisations of emerging risk

Stage Two Alert: Resource. This may be issued some weeks or months after the stage one alert for the provision of resources, tools and learning materials to help mitigate risk identified in stage one

Stage Three Alert: Directive. At this stage organisations are required to confirm they have implemented specific solutions or actions to mitigate the risk

1.3 Field Safety Notices – communications sent out by medical device manufacturers, in connection with field safety corrective actions. They are placed on the MHRA website, and do not require further action unless the Trust is contacted directly by the manufacturer. If the MHRA receive sufficient supporting data, the field safety notice is escalated to an alert for trusts to action.
The Purchasing Manager keeps all responses and where necessary reports back to the NHS Supply Chain. Copies of alerts are sent to the Safety Alerts Liaison Officer for information.

1.4 Medicines Alerts

MHRA Drug Safety Alerts are circulated via the NHS CAS system, and received directly by the Pharmacy department who action them as appropriate. When required, medicines alerts and action plans are discussed at the Drugs and Therapeutics Group (+/- Medicines safety Group for information/action where needed)

There is currently a system in place to implement notice for medicines alerts over a 24-hour period via the Pharmacy Department. Drug Alerts for urgent action / product recall are received from the Trent Medicines Information Centre (TMIC), at Leicester Royal Infirmary; to the Medicines Information Pharmacist and Pharmacy Logistics Manager or Deputy who will manage the recall process Monday to Friday 9am to 5pm. A procedure is in place within the Pharmacy department for action to be taken if an urgent drug alert is received outside of normal working hours.

Medication Side Effects - are reported using the national yellow card scheme found at the back of the BNF (or an online form can be accessed via the MHRA or 'Yellow card scheme' website) to the MHRA and the Commission on Human medicines. The medicines information department within Pharmacy or outside normal working hours the on call Pharmacist can be called for advice on any medicine related incidents and to encourage reporting. The Yellow Card Scheme is a voluntary scheme run by the MHRA and the Commission on Human Medicines, which is used to collect information from both health professionals and the general public on suspected side effects

1.5 The Chief Medical Officer (CMO) Alerts – are circulated via the CAS system; and disseminated to appropriate areas e.g. Pharmacy, Emergency Department and via the Division/Business Unit links.

1.6 Health Protection Agency

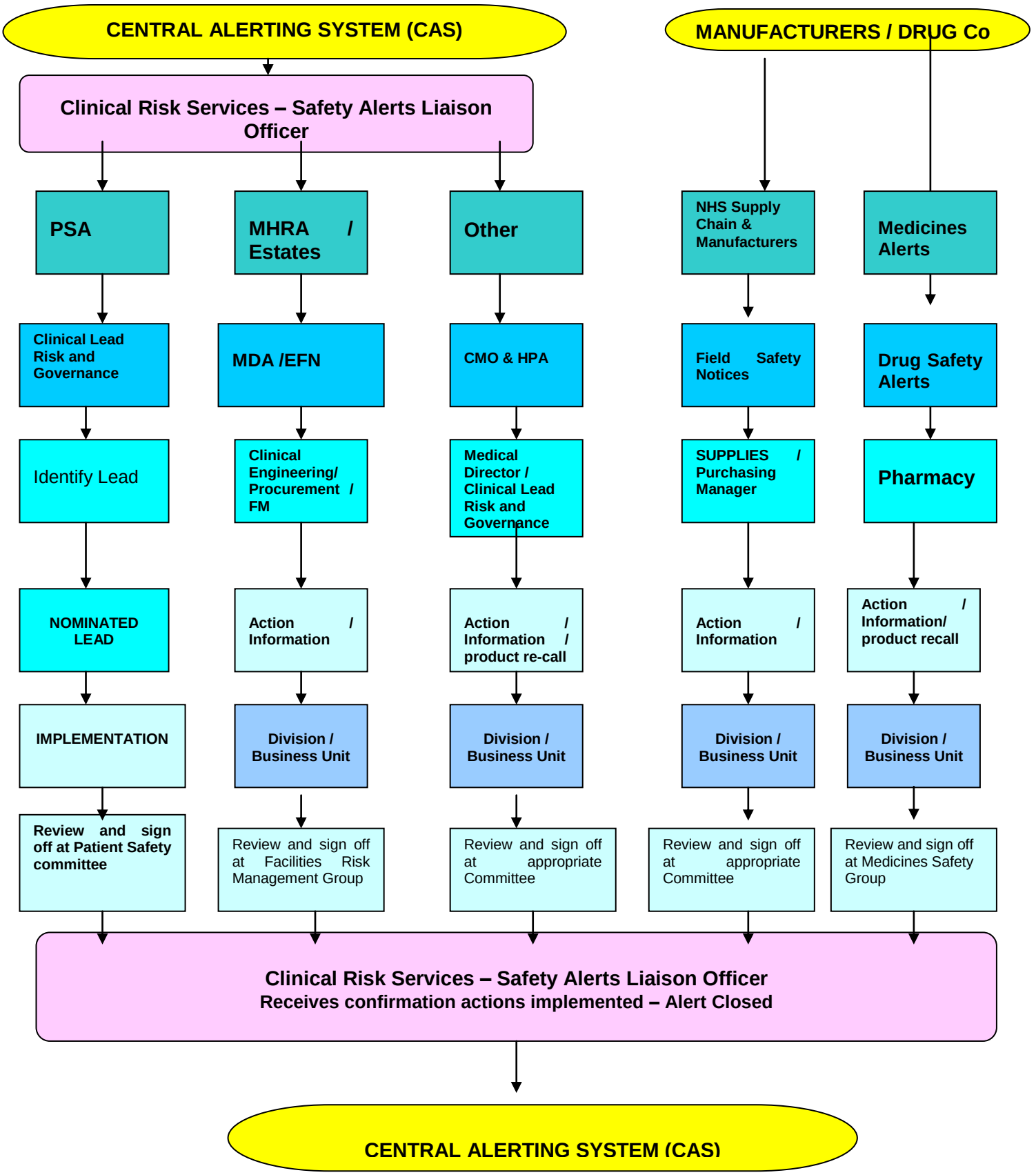
The Health Protection Agency (HPA) is an independent body that protects the health and well-being of the population. The Health Protection Agency's role is to provide an integrated approach to protecting UK public health through the provision of support and advice to the NHS, local authorities, and emergency services. The Agency plays a critical role in protecting people from infectious diseases and in preventing harm when hazards involving chemicals, poisons or radiation occur. They also prepare for new and emerging threats, such as a bio-terrorist attack or a virulent new strain of disease.

1.7 Internal Alerts

The Trust has a process for reporting incidents on Incident forms and risk assessment forms for entry onto the Trust Risk Register. Internal alerts may need to be issued by the Trust to provide rapid and effective distribution of information e.g. following a Serious Incident (SI). An internal alert following SI will only be distributed following the agreement of the Director of Patient Experience, Medical Director or Deputy.
The distribution process will follow the CAS procedure with the exception that progress of actions will not be reported to the DH.

1.8 Estates and Facilities Notifications - are circulated via the NHS CAS system, to SALO who sends to the Deputy Head of Facilities Management for review and responses to any actions.

Appendix 2 Alert Dissemination Flowchart – Clinical Risk Services



Appendix 3 Overview of Trust Systems

System	Processes	Description
Central Alerting System	Supplies (CAS), Medical Devices (CAS), Pharmacy (CAS)	National system for the dissemination and reporting of national safety alerts
Agresso	Supplies (CAS), Supplies (FSN), Medical Devices (FSN)	Finance system used for processing payments to suppliers
NHS Supply Chain	Supplies (CAS), Supplies (FSN), Medical Devices (FSN)	National NHS Supply Chain catalogue
hTrak	Supplies (CAS), Supplies (FSN)	Stock and usage solution to automate inventory and provide functionality for product traceability
JAC	Pharmacy (via CAS), Pharmacy (via LRI)	Pharmacy inventory management system. Used for ordering drugs, recording batch number of unlicensed drugs, recalling drugs dispatched to clinical areas
AIMS	Medical Devices (CAS), Medical Devices (FSN), Medical Devices (Datix)	Clinical Engineering inventory management system. Includes a record of the last known location of medical equipment
Datix	Medical Devices (Datix)	Patient safety and risk management software for incident reporting and adverse events

Appendix 4 Alert Flowcharts

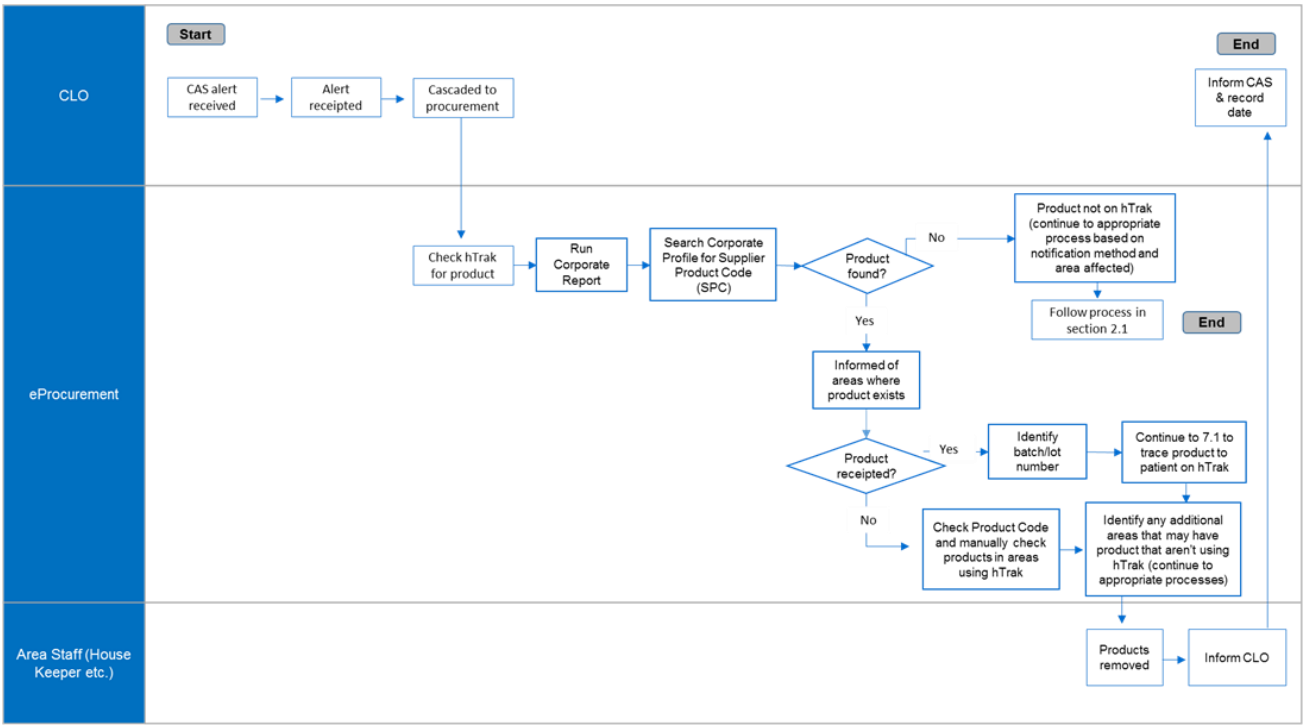
The following processes steps outline the actions that must be taken when a product recall alert is received via CAS, FSN, Datix or LRI.

*hTrak should be utilised by the Purchasing department in the initial instance to check if the product is recorded on the system. The responsibility of the hTrak processes sits with the Supplies eProcurement Teams. Notification sent to dhft.Supplies@nhs.net will be checked to first determine if a product is on hTrak.

See process 7.1 for a process map detailing how to check if a product is on hTrak.

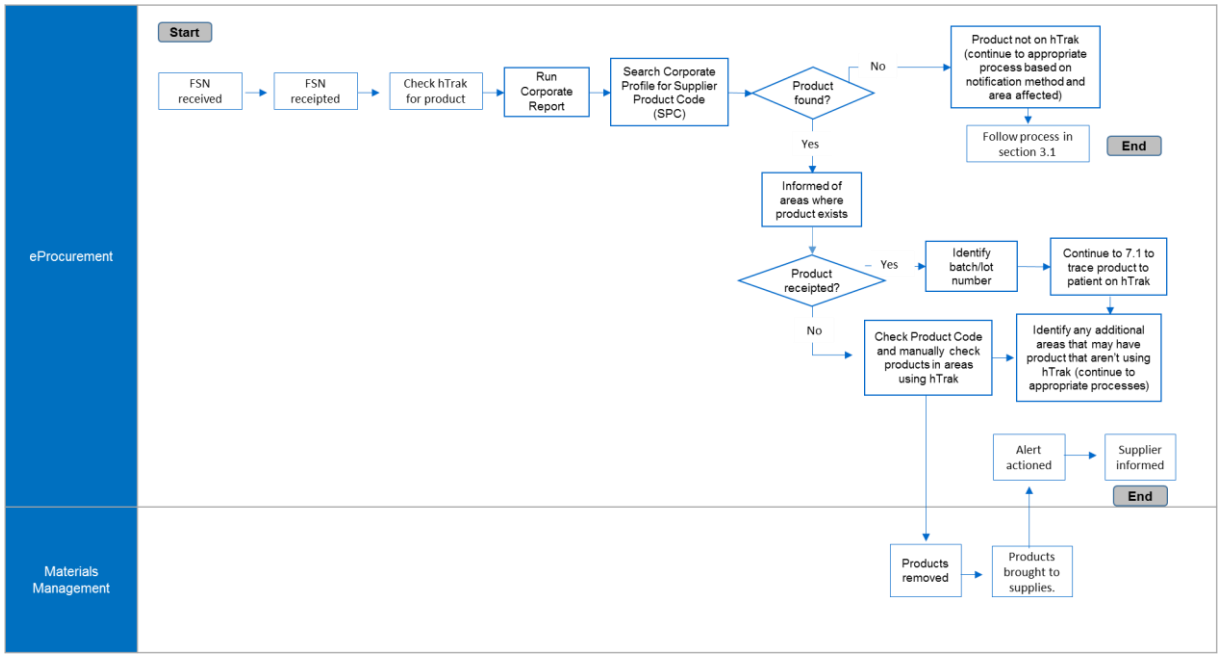
Step 1: What is the Source of Alert?	Step 2: Which Area is Affected?	Step 3: Verify whether product is on hTrak	Step 4: If not on hTrak, process to follow
CAS	Supplies	Section 1.1	Section 2.1
	Medical Devices	*N/A*	Section 2.2
	Pharmacy (Drugs)	*N/A*	Section 2.3
FSN	Supplies	Section 1.2	Section 3.1
	Medical Devices	*N/A*	Section 3.2
	Pharmacy (Drugs)	*N/A*	Section 3.3
Datix	Medical Devices	*N/A*	Section 4.1
LRI	Pharmacy (Drugs)	*N/A*	Section 5.1
Via a Managed Service	Managed Services	*N/A*	Section 6.1

Section 1.1: Supplies CAS Alert – Verify whether a product is on hTrak



- CAS alert is received for supplies and receipted in by the *CAS Liaison Officer (SALO)*
- *CAS Liaison Officer* cascades information to Procurement
- Supplies and eProcurement Team notified of product recall (dhft.Supplies@nhs.net)
- Run corporate report
- Search for SPC in Corporate Profile
- If the product is not found in the report, the product is not on hTrak. Continue to process in section 2.1
- If the product is found, the report will detail what areas the product is in
- If the product is receipted, identify batch/lot number and continue to 7.1 to trace product to location/patient.
- If the product is not receipted, check product code and manually check products in areas using sTrak software
- Inform area staff (house keepers etc.) for affected areas so that they can locate and remove products
- Inform SALO of action taken
- SALO informs and date stamps CAS

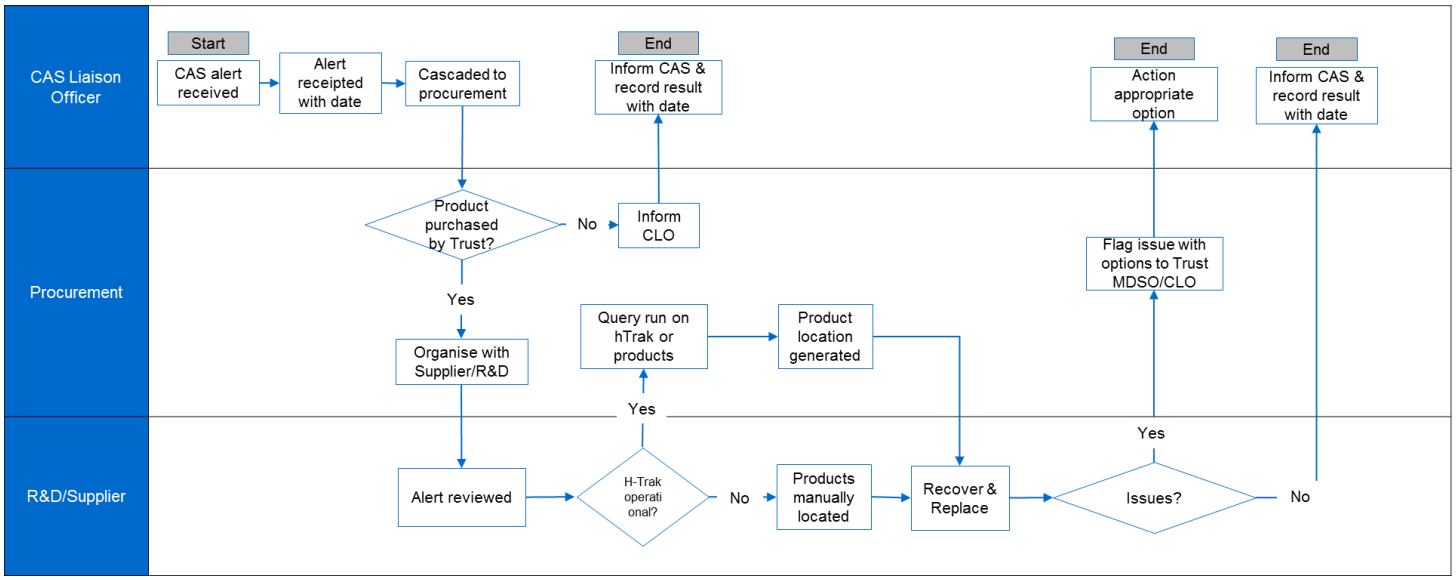
Section 1.2: Supplies FSN – Verify whether a product is on hTrak



- FSN alert received from a supplier
- *Procurement* receipt in alert
- Run corporate report
- Search for SPC in Corporate Profile
- If the product is not found in the report, the product is not on hTrak. Continue to process in section 3.1
- If the product is found, report will detail what areas the product in.
- If product is receipted, identify batch/lot number and continue to 7.1 to trace product to location/patient.
- If product not receipted, check product code and manually check products in areas using sTrak software
- Dispatch materials management to locate and remove relevant products
- Inform supplier of action taken

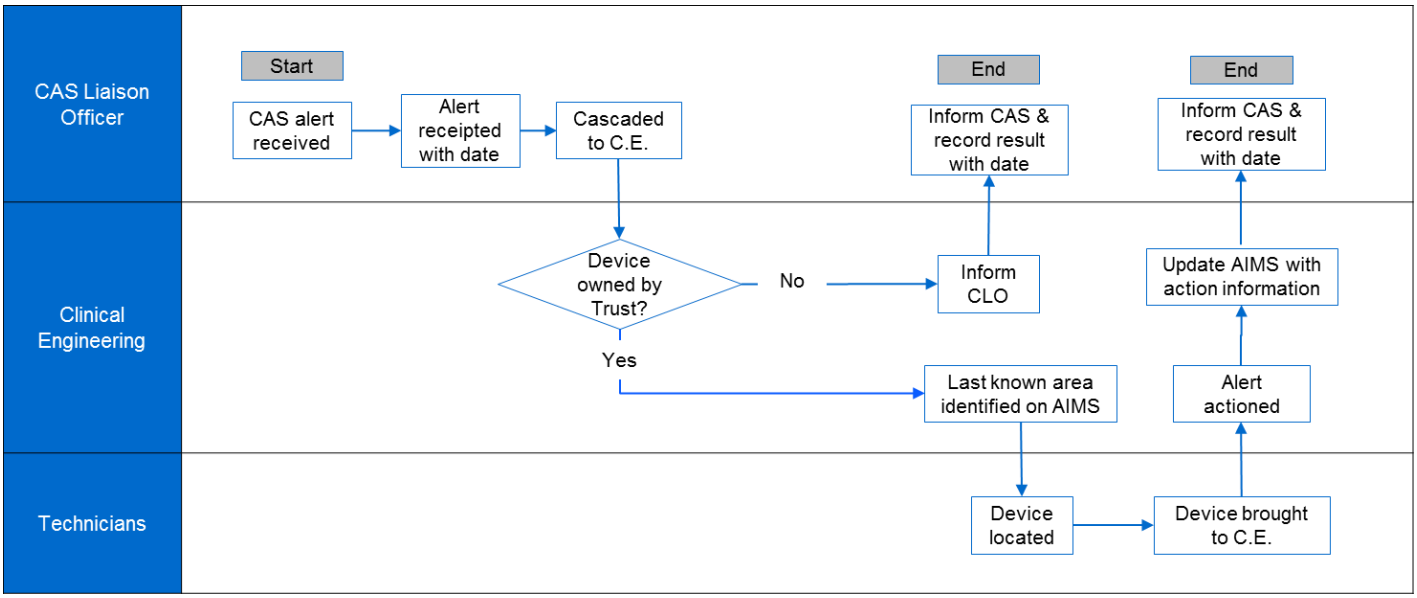
CAS Alerts

Section 2.1: Product Recall Process – Supplies (CAS)



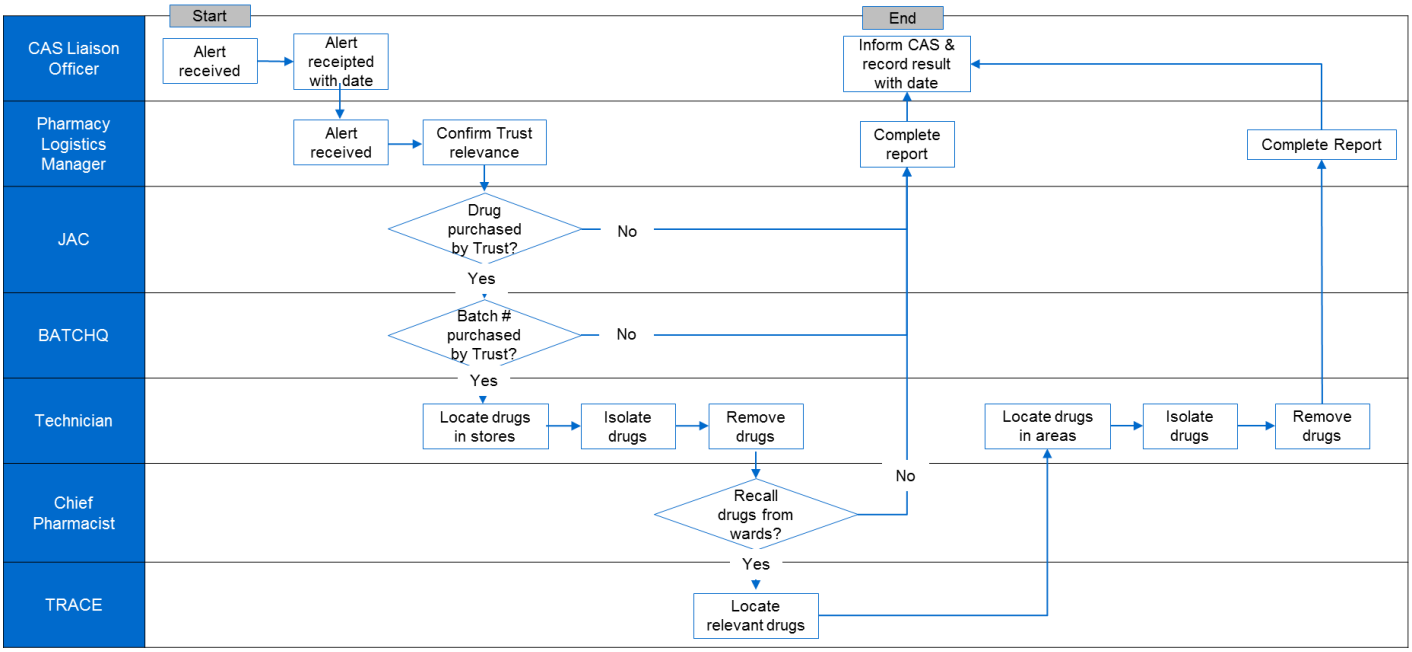
- CAS alert is received for supplies and receipted in by the *CAS Liaison Officer (SALO)*
- *CAS Liaison Officer* cascades information to Procurement
- If the product was not purchased by the Trust, *Procurement* inform the SALO and *SALO* informs CAS
- If the product was purchased by the Trust, *Procurement* contacts R&D/Supplier to organise recovery and replacement
- *R&D/Supplier* review the Alert. If hTrak is operational, *Procurement* run a query on hTrak and generate the product location. *R&D/Supplier then* recover and replace the item
- If hTrak is not operational, *R&D/Supplier* locate products manually and then recover and replace
- If there are no issues, *R&D/Supplier* inform the SALO. *SALO* informs CAS and records result with date
- If there are issues, *Procurement* flag the issue as well as options to MDSO/SALO
- *SALO* action appropriate option

Section 2.2: Product Recall Process – Medical Devices (CAS)



- CAS alert is received for medical devices and receipted in by *SALO*
- *SALO* cascades information to *Clinical Engineering (CE)*
- If the device is not owned by the Trust, *CO* informs SALO and *SALO* informs CAS
- If the device is owned by the trust, *CE* identifies last known area on AIMS
- *Technicians* locate the device and bring to CE
- *CE* action the alert and inform SALO
- *CE* update AIMS with action information
- *SALO* informs CAS and records result with date

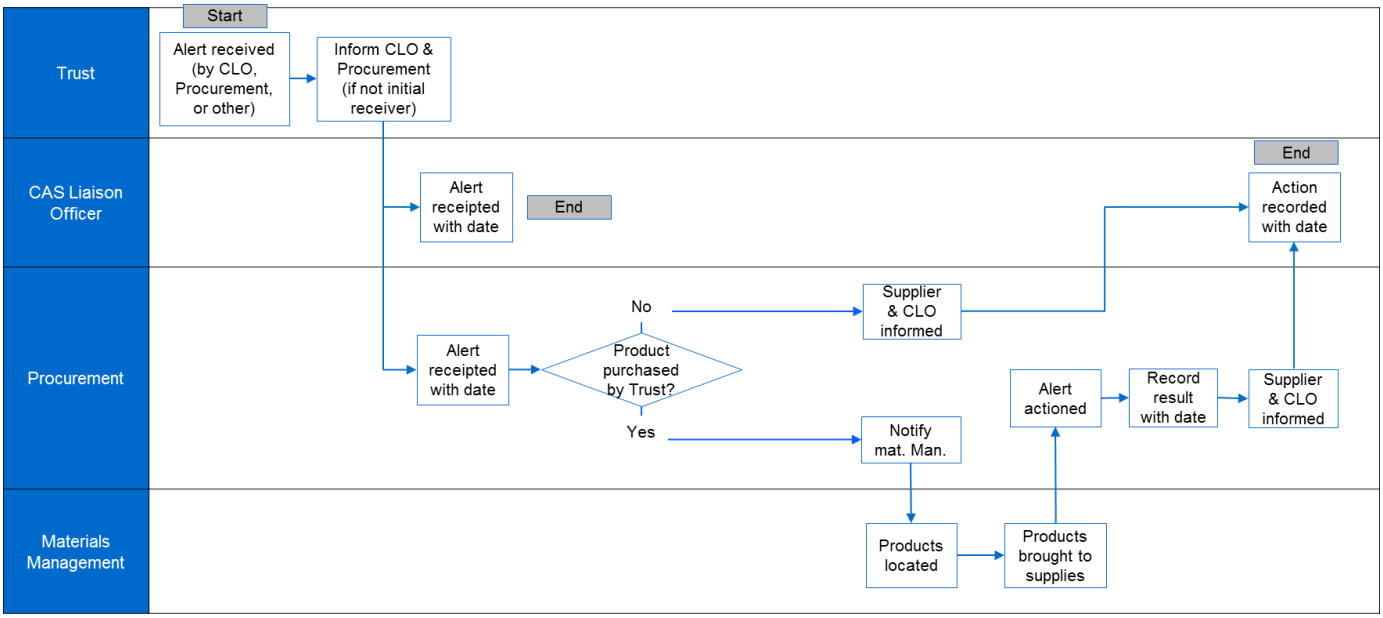
Section 2.3: Product Recall Process – Pharmacy (CAS)



- *SALO* receives alert from CAS regarding pharmacy and receipts in
- *SALO* informs Pharmacy Logistics Manager (PLM)
- *PLM* checks on JAC if drug was purchased by Trust
- If *JAC* shows that the drug was not purchased by the Trust, the *PLM* completes a report and informs SALO. *SALO* then informs CAS
- If *JAC* shows the drug was purchased by the Trust, *PLM* checks if the batch number was purchased by the Trust using BATCHQ. If not, *PLM* completes report and informs SALO. *SALO* informs CAS
- If the batch number was purchased by the Trust, a *Technician* locates the drug in stores, isolates the drugs, and removes them
- The *Chief Pharmacist* checks if the drugs need to be recalled from the wards. If not, *Chief Pharmacist* completes report and informs SALO. *SALO* then informs CAS
- If the drugs do need to be recalled from the wards, *TRACE* used to locate the relevant drugs
- *Technicians* locate the drugs in the areas, isolate the drugs and remove them
- *PLM* completes report and informs SALO. *SALO* informs CAS

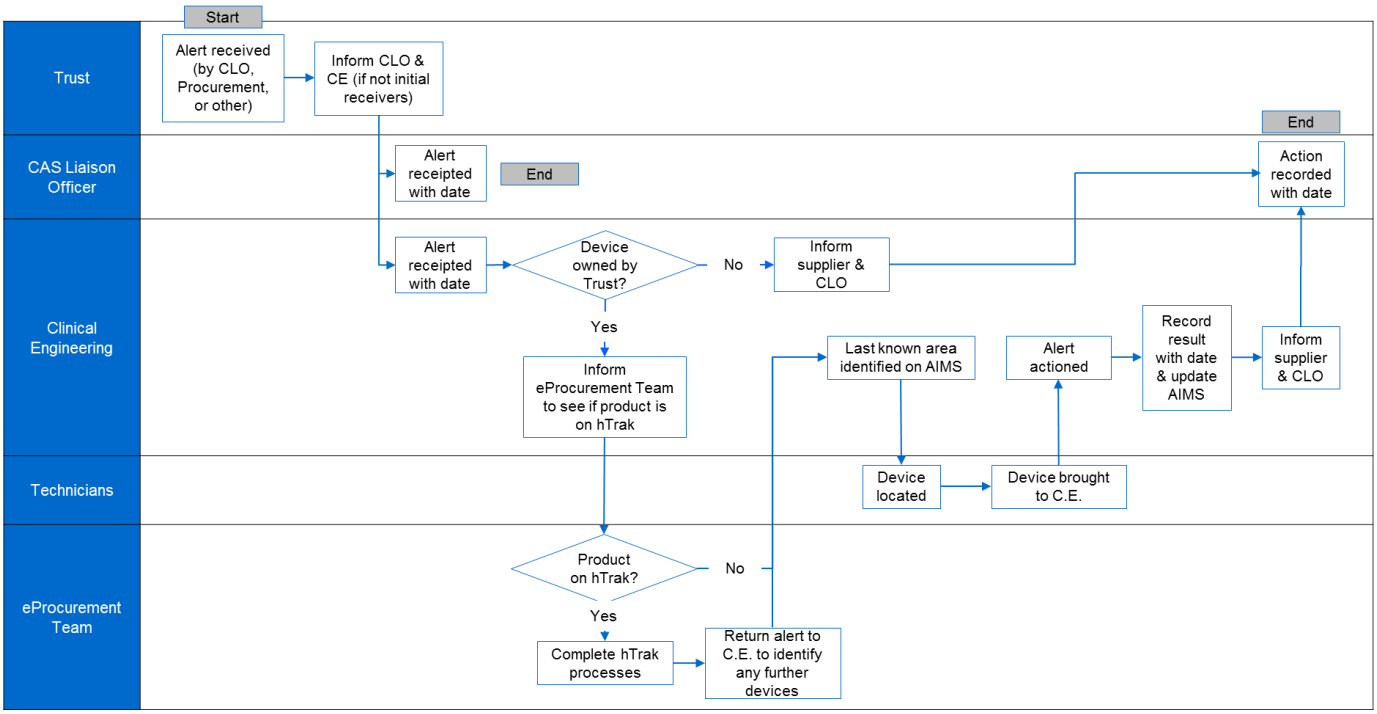
Field Safety Notices

Section 3.1: Product Recall Process – Supplies (FSN)



- FSN alert received from a supplier. Receiver informs SALO and Procurement
- *SALO* receipt in alert with date
- *Procurement* receipt in alert
- If product was not purchased by Trust, *Procurement* inform supplier and SALO
- If the product was purchased by the Trust, *Procurement* inform Materials Management (Mat Man)
- *Mat Man* locate the products and bring to supplies
- *Procurement* action the alert and record result with date
- *Procurement* inform supplier & SALO
- *SALO* record action taken with date

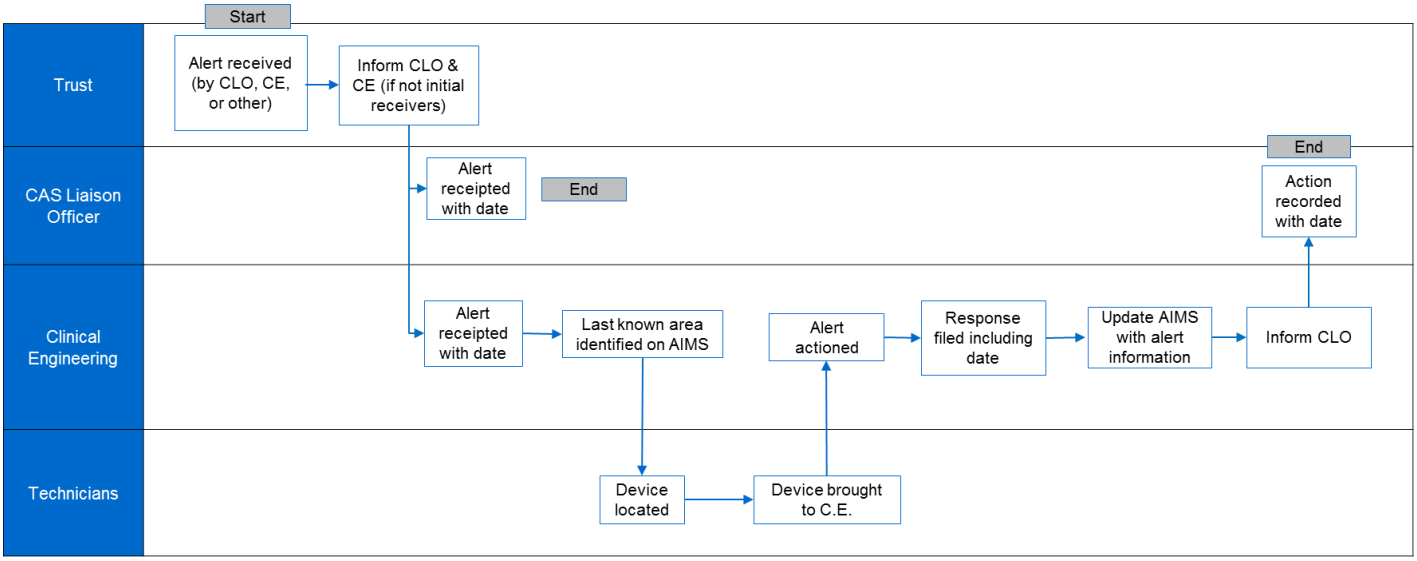
Section 3.2: Product Recall Process – Medical Devices (FSN)



- FSN alert received regarding medical devices by the Trust. Receiver informs SALO and CE (if not initial receivers)
- *SALO* receipts in alert with date
- *CE* receipts in alert with date
- If the device is owned by the Trust, *CE* inform eProcurement Team to see if the product is on hTrak
- If product is on hTrak, *eProcurement Team* complete hTrak processes and then return alert to C.E. to identify if there are any further devices
- *CE* identify last known area on AIMS
- *Technicians* locate device and bring to CE
- *CE* action alert, file response, and update AIMS
- *CE* inform supplier and SALO
- *SALO* record action taken with date

Datix Processes

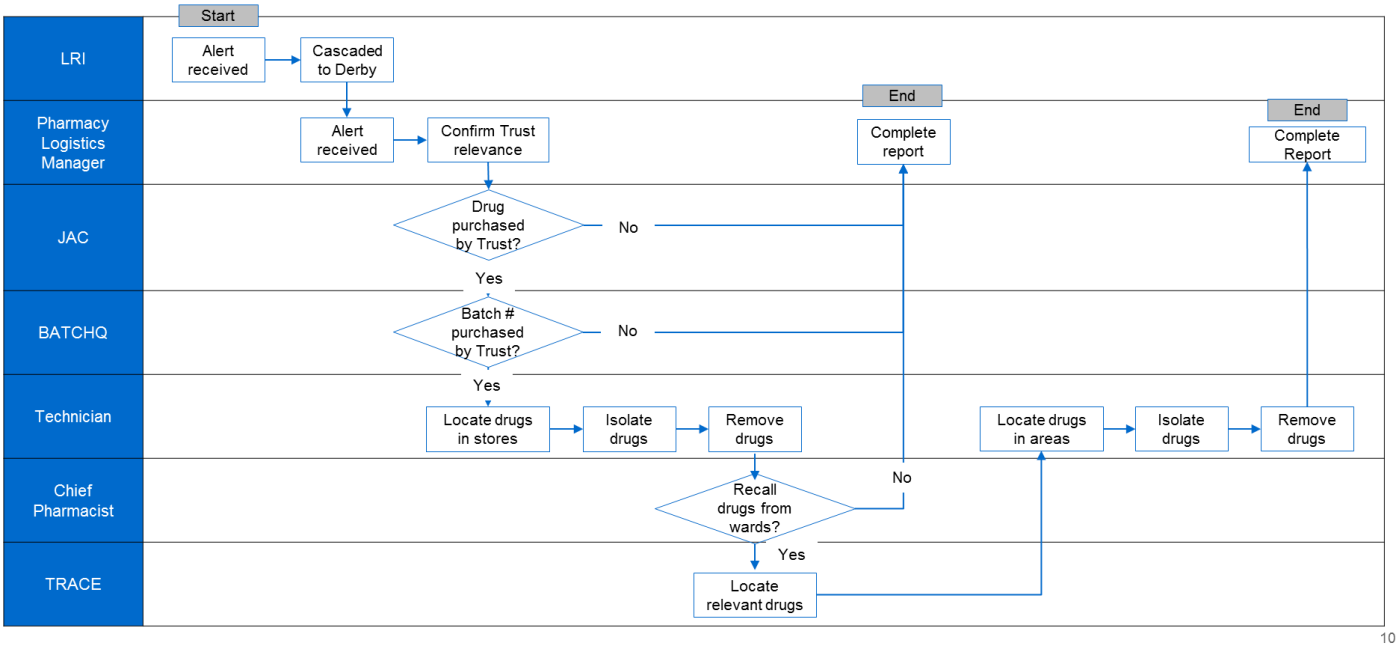
Section 4.1: Product Recall Process – Medical Devices (Datix)



- Datix alert for medical devices received by the Trust (could be by various people). Receiver informs SALO and CE (if not initial receivers)
- *SALO* receipts in alert with date
- *CE* receipts in alert with date
- *CE* identify last known area on AIMS
- *Technicians* locate the device and bring to CE
- *CE* action the alert and file the response with the date
- *CE* update AIMS with recall information
- *CE* inform SALO of result
- *SALO* record action taken with date

LRI

Section 5.1: Product Recall Process – Pharmacy (via LRI)

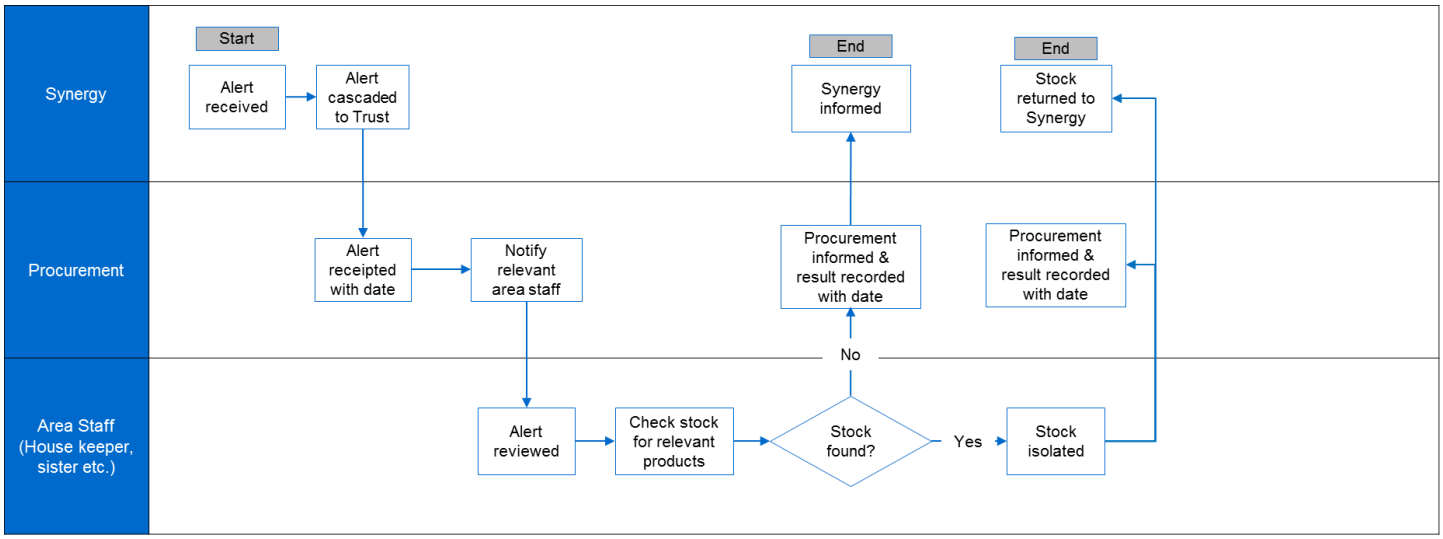


- Alert received via LRI and cascaded to Derby
- *PLM* receives alert
- *PLM* checks on JAC if drug was purchased by Trust.
- If the drug was not purchased the *PLM* completes report
- If the drug was purchased by the Trust, *PLM* checks on BATCHQ if the batch number was purchased by the Trust
- If the batch number was purchased by the Trust, *Technicians* locate the drugs in stores, isolate the drugs and remove them
- *Chief Pharmacist* checks if the drugs need to be recalled from the wards. If not, the *Chief Pharmacist* completes a report
- If the drugs do need to be recalled from the wards, the relevant drugs are located using *TRACE*
- *Technicians* locate the drugs in areas, isolate the drugs, and remove them
- *PLM* completes a report

Managed Services

Section 6.1: Product Recall – Managed Services

Note: Products provided by Synergy are used as an example in this process flow



- Alert is received from *Synergy* (or other managed service provider) and cascaded to the Trust
- *Procurement* receive alert and notify relevant Area Staff
- *Area Staff* review alert and check stock for relevant products
- If the stock is not found, Procurement is informed and *Procurement* inform Synergy
- If the stock is found, *Area Staff* isolate the stock and return to Synergy

hTrak Process

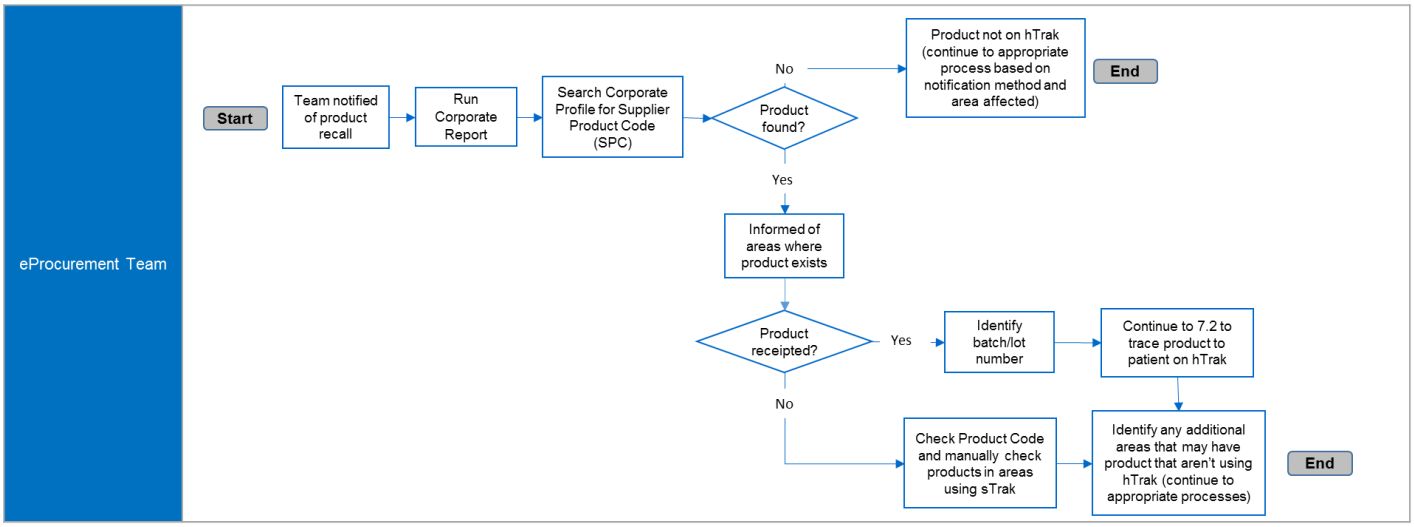
The Trust can utilise the hTrak system to identify products, in particular:

- where stock is physically in the Trust
- on which patients (if applicable) the products have been used

Once the product has been located and removed from the shelves, stock levels also need to be adjusted in hTrak.

The processes below detail how to run reports to identify in a product is on hTrak, using hTrak to identify patients, as well as adjusting stock levels. At the end of these processes a report in hTrak can be run to list recalled products and use this as a check against information sent from the supplier.

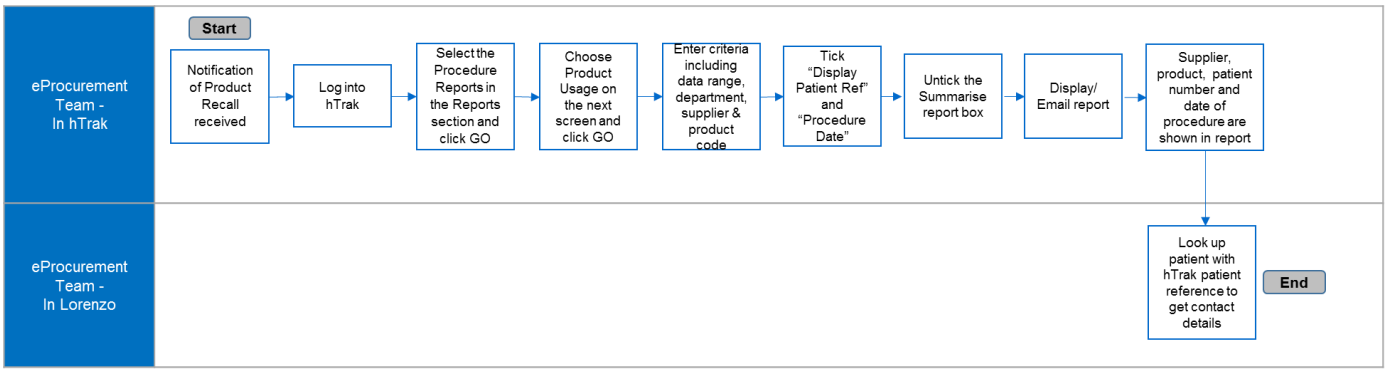
Section 7.1: Identifying if a product is on hTrak



- *eProcurement Team* notified of product recall (via FSN or hTrak mailbox – dhft.htrakhelpline@nhs.net)
- Run corporate report
- Search for SPC in Corporate Profile
- If the product is not found in the report, the product is not on hTrak. Continue to appropriate process based on notification method and area affected (See table in section 4)
- If the product is found, report will detail what areas the product in.
- If product is receipted, identify batch/lot number and continue to 7.2 to trace product to location/patient.
- If product not receipted, check product code and manually check products in areas using sTrak software
- Identify any additional areas that may have the product that aren't using and continue to appropriate process (based on the table in section 4)

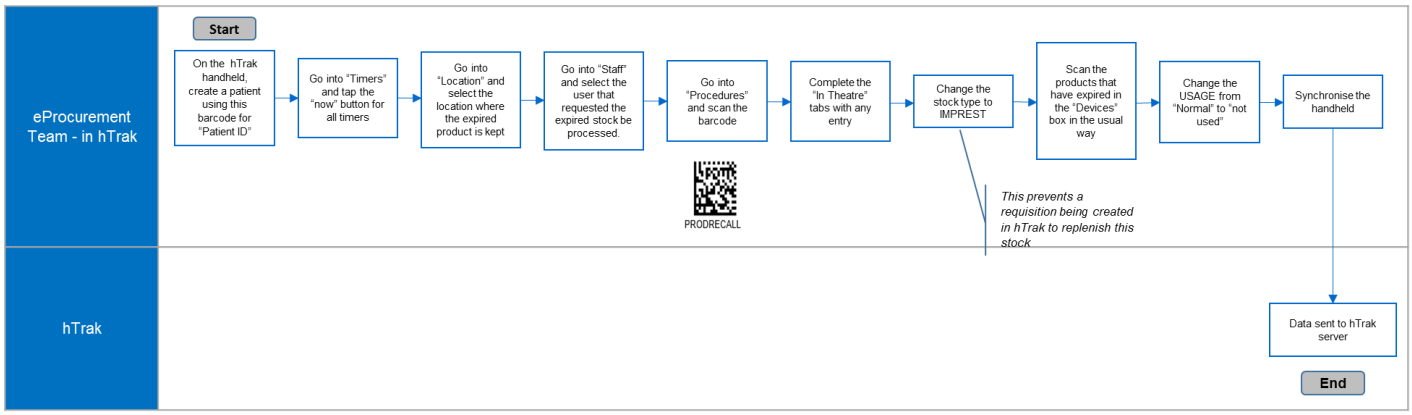
Section 7.2: Identifying patient in hTrak for product recall

Note: See detailed instructions including screenshots in Appendix 6



- A notification of a product recall has been received and the area is hTrak operational
- *eProcurement* logs into hTrak, selects the Procedure Reports in the Reports section and clicks GO
- Choose product usage and click GO
- Enters criteria including date range, department, supplier, and product code
- Tick "Derby Patient Ref" and "Procedure Date"
- Untick the summarise report box
- hTrak produces detailed report including supplier, product, patient number, and date of procedure
- *eProcurement/Finance* looks up patient in Lorenzo to get contact details

Section 7.3: Adjusting Stock Levels in hTrak



- *eProcurement* create a patient in hTrak handheld using patient ID barcode
- Go into Timers and tap the “now” button for all timers
- Go into Location and select the location where the expired product is kept
- Go into Staff and select the user that requested the expired stock to be processed
- Go into Procedures and scan the PRODRECALL barcode
- Complete the In Theatre tabs with any entry
- Change the stock type to IMPREST to prevent a requisition being created in hTrak to replenish this stock
- Scan the products that have expired in the Devices box in the usual way
- Change the USAGE from Normal to “not used”
- Synchronise the hTrak handheld
- Data is automatically sent to the hTrak server

8. Appendix 4 Division Coordinators

Division	Speciality	Designation
Corporate Services	Infection Control	Infection Control Specialist Nurses
	Facilities	Deputy Head of Facilities Management
	Medical Devices	Clinical Specialist & Equipment Library Manager
Division of Medicine and Cancer	Acute Medicine Business Unit	Clinical Governance Facilitator
	Specialist Medicine Business Unit	Clinical Governance Facilitator
	Cancer Business Unit	Clinical Governance Facilitator
Division of Diagnostics, Surgery and Anaesthetics	All	Clinical Governance Coordinator
	Pathology Services	Quality Manager
	Imaging	Superintendent Radiographer
Division of Integrated Care	Community & Rehabilitation Business Unit	Clinical Governance Facilitator
	Pharmacy	Chief Technician – Logistics Manager or Deputy (& Medicines Information Pharmacist where applicable) & Patient Safety/Clinical Governance Pharmacist.
	Maternity & Gynaecology	Audit Assistant & Clinical Governance Facilitator
	Children's Services	Patient Safety Coordinator

9. Appendix 5 MDA Action plan Template

MDA Action plan

MDA Number: MDA/…	
Alert Description:	
Division:	**Trust Wide/Ward / Department:**
Actions	**Action completed by /Date**
Equipment not used / Alert not applicable	
MDA forwarded to all relevant areas for action / information List areas	
Action Required:	
Response:	
Copy of action plan forwarded to Safety Alerts & Directorate Coordinator Date:	
Deadline (action to have been completed) by:	
Actions completed By: Name: **Date:**	

10. Appendix 6 Patient Safety Action Plan

Action plan developed in response to:

Stage : Issued :
(1,2 or 3)
Action plan lead- **Overseeing Committee**-Patient Safety Committee

Due to be completed and signed off --

No	*RECOMMENDATION*	*AGREED ACTION*	*LEVEL (Individual Specialty Directorate Organisational)*	*PERSON RESPONSIBLE*	*TIMESCALE (Expected)*	*EVIDENCE OF COMPLETION*	*ACTUAL DATE OF COMPLETION*
1							
2							
3							
4							
local	Share initial action plan with Patient safety committee to establish projected actions and an estimation of timescales						
local	Provide regular updates to Patient Safety Committee regarding progress and immediately escalate any emerging risks to sign off by completion date						

11. Appendix 7 Table of Governance

Type of Alert	Receipt	Distribution	Overseeing Committee/Group	Closure
PSA / DH / CMO / HPA & Internal Alerts	Received by SALO from CAS.	Forwarded to the Clinical Lead Risk and Governance to ascertain appropriate individual lead/group/committee. The SALO forwards the alert to the Division/|Business Unit Coordinator for information (if alert is to be led corporately); or for action (if a specialty specific response is required).	Patient Safety Committee	Lead individual informs SALO of completion of alert who will update national CAS database.
MHRA (MDA)	Received by SALO from CAS	The SALO forwards to the Clinical Engineer, Equipment Library Manager & Procurement Manager to ascertain if the equipment is utilised within the Trust. Alert sent to the Division/|Business Unit Contacts for action or information	Medical Devices Committee	Lead individual informs SALO of completion of alert who will update national CAS database
EFN	Received by SALO from CAS	The SALO forwards to Facilities Management to ascertain if the alert is applicable within the Trust. If corporate action required the alert is addressed by Facilities Management. The SALO will forward to Division/|Business Unit Coordinator for action if a specialty specific response is required	Facilities Management Risk Group	Lead individual informs SALO of completion of alert who will update national CAS database

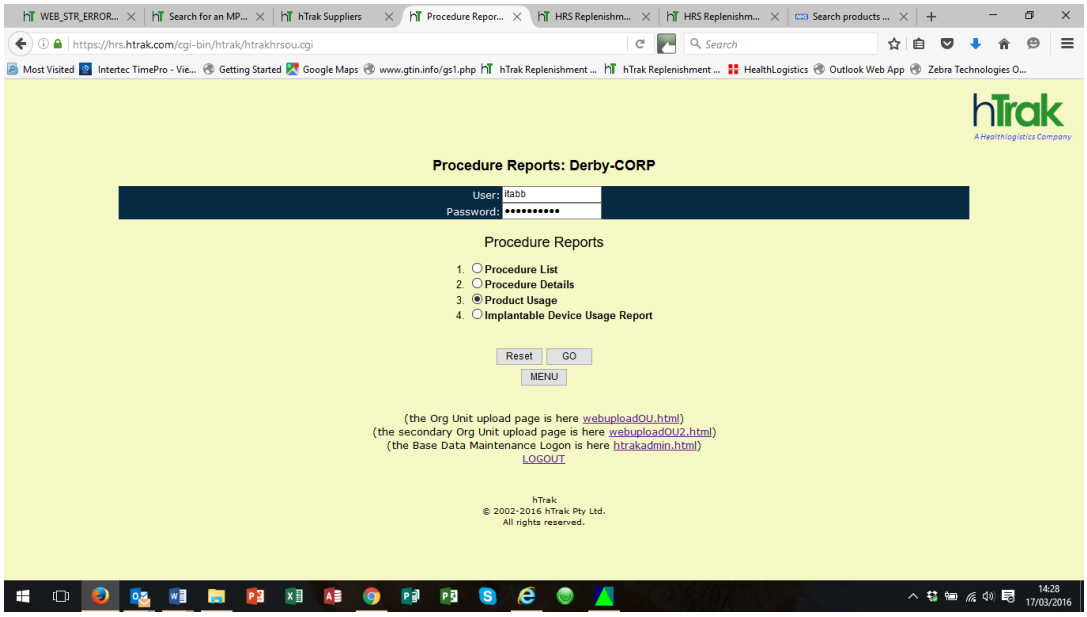
Type of Alert	Receipt	Distribution	Overseeing Committee/Group	Closure
MHRA Medicines Alert (includes Drug safety updates, warnings, alerts and recalls)	Alerts received by Pharmacy	Pharmacy locally actions alert. Forwarded to Division/|Business Unit coordinators for information/action	Drugs and Therapeutics Group (+/- Medicines Safety Group for information/action where needed)	Pharmacy confirms closure (+/- informing SALO of completion of specific alerts on national CAS database where needed).
NHS England Medicines 'Patient Safety Alerts'	Alerts received by the Medicines Safety Officer and SALO from CAS.	Forwarded to Division/|Business Unit Coordinator for action / information; or for action (if a specialty specific response is required). This process is overseen by the Medicines Safety Officer in conjunction with the Medicines Safety Group.	Medicines Safety Committee & Patient Safety Committee.	Lead individual informs SALO of completion of alert who will update national CAS database.
NHS Supply Chain Alerts	Field Safety Notices are received by the Trust NB: may be direct from the supplier	The SALO forwards to the Clinical Engineer, Equipment Library Manager & Procurement Manager to ascertain if the equipment is utilised within the Trust. Alert sent to the Division/|Business Unit Contacts for action or information.	Appropriate Trust Committee e.g. Medical Devices Committee	Lead individual informs SALO of completion of alert who will update national CAS database
Internal Alerts	Identified by the Director of patient Experience and Chief Nurse/Medical Director	Forwarded to Division/|Business Unit Coordinator for action / information; or for action (if a specialty specific response is required).	Appropriate Trust Committee e.g. Infection Control Committee, Patient Safety Committee	Lead individual informs SALO of completion of alert who will update national CAS database

12. Appendix 7 Identifying a patient in hTrak

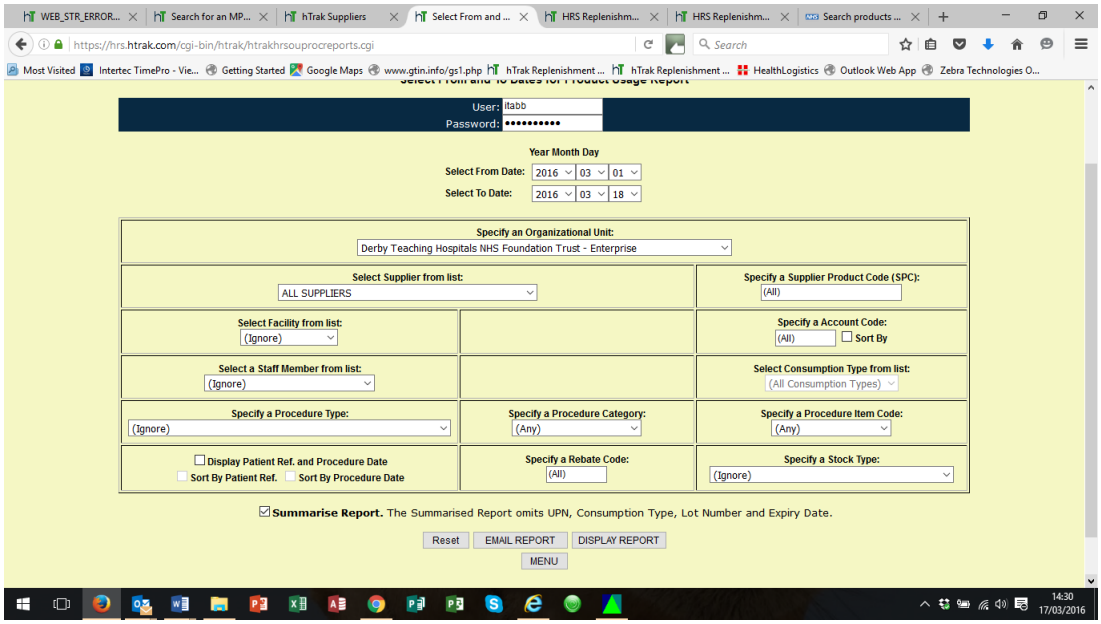
The steps below show how to identify a patient in hTrak based on the products which have been used on them.

1. Log into hTrak and select the Procedure Reports in the Reports section and click GO:

2. Choose Product Usage on the next screen and click GO:



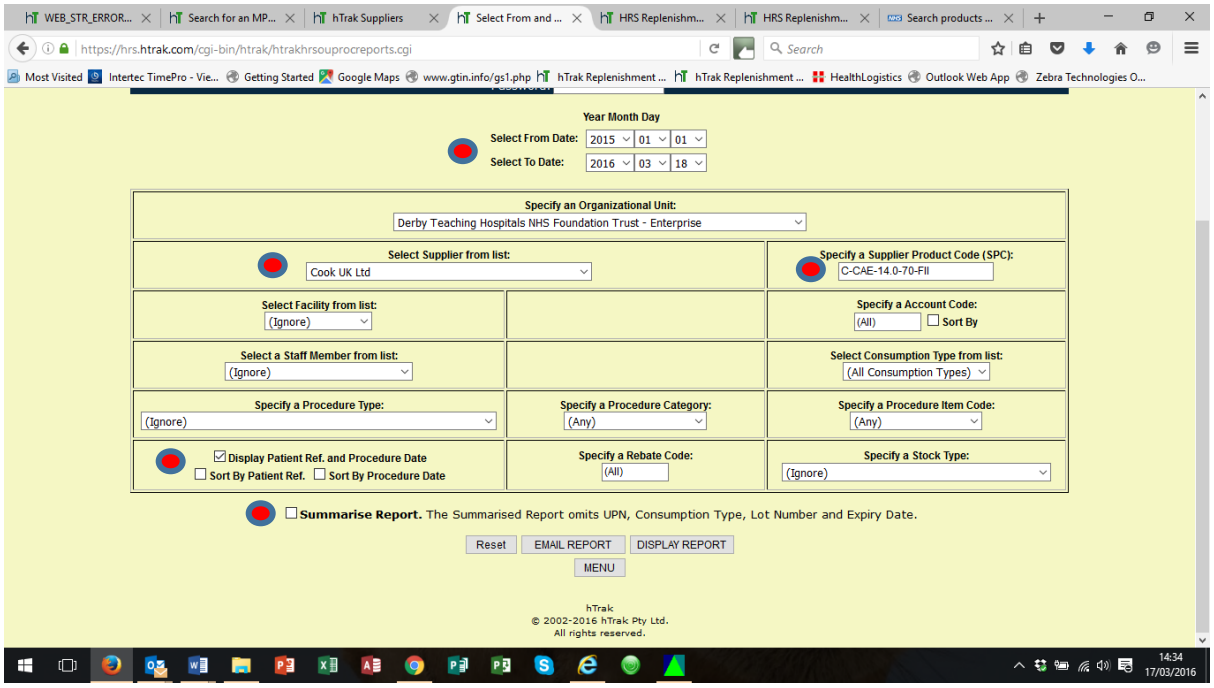
3. Input criteria into the next screen:



- Select date range and decide if recall is department specific – if not then leave the Organisational Unit at the highest level (this is the default and shown in the example above)
- Enter supplier (Cook in this example) in the supplier list and to the right of that put in the product code

4. Tick the Display Patient Ref and Procedure Date and untick the Summarise report box.

   Screen will now look like this:



5. Choose to display or email the report.

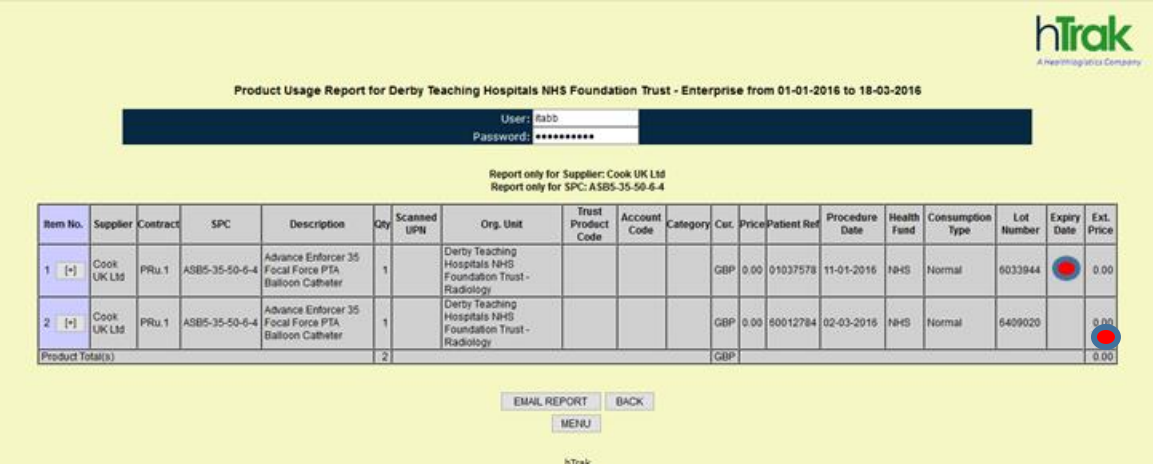
The displayed report will look like this:

Item No.	Supplier	Contract	SPC	Description	Qty	Scanned UPN	Org. Unit	Trust Product Code	Account Code	Category	Cur.	Price	Patient Ref	Procedure Date	Health Fund	Consumption Type	Lot Number	Expiry Date	Ext. Price
1 [+]	Cook UK Ltd	PRu.1	C-CAE-14.0-70-FII	Frova Intubating Introducer	1	00827002236462	Derby Teaching Hospitals NHS Foundation Trust - General Day Case	C-CAE-14.0-70-FII	3032	FES	GBP	55.00	01006062	03-08-2015	NHS	Normal			55.00
2 [+]	Cook UK Ltd	PRu.1	C-CAE-14.0-70-FII	Frova Intubating Introducer	1	00827002236462	Derby Teaching Hospitals NHS Foundation Trust - General Day Case	C-CAE-14.0-70-FII	3032	FES	GBP	55.00	474225	12-06-2015	NHS	Normal			55.00
3 [+]	Cook UK Ltd	PRu.1	C-CAE-14.0-70-FII	Frova Intubating Introducer	1	00827002236462	Derby Teaching Hospitals NHS Foundation Trust - General Day Case	C-CAE-14.0-70-FII	3032	FES	GBP	55.00	584059	23-11-2015	NHS	Normal			55.00
4 [+]	Cook UK Ltd	PRu.1	C-CAE-14.0-70-FII	Frova Intubating Introducer	1	00827002236462	Derby Teaching Hospitals NHS Foundation Trust - General Day Case	C-CAE-14.0-70-FII	3032	FES	GBP	55.00	777255	08-07-2015	NHS	Normal			55.00
5 [+]	Cook UK Ltd	PRu.1	C-CAE-14.0-70-FII	Frova Intubating Introducer	1	00827002236462	Derby Teaching Hospitals NHS Foundation Trust - General Day Case	C-CAE-14.0-70-FII	3032	FES	GBP	55.00	852489	14-08-2015	NHS	Normal			55.00
6 [+]	Cook UK Ltd	PRu.1	C-CAE-14.0-70-FII	Frova Intubating Introducer	1	00827002236462	Derby Teaching Hospitals NHS Foundation Trust - General Day Case	C-CAE-14.0-70-FII	3032	FES	GBP	55.00	930725	15-12-2015	NHS	Normal			55.00

All required information should be provided. The supplier, product, and patient number are shown as well as the date of the procedure.

6. To look at a particular procedure click on the {+} symbol on the left hand side of the procedure

7. If the recall is only for a specific Lot Number of a product, follow the same steps as above and then extract the procedures where that product and Lot Number were used:



hTrak

Product Usage Report for Derby Teaching Hospitals NHS Foundation Trust - Enterprise from 01-01-2016 to 18-03-2016

User: ifabb
Password: ••••••••••

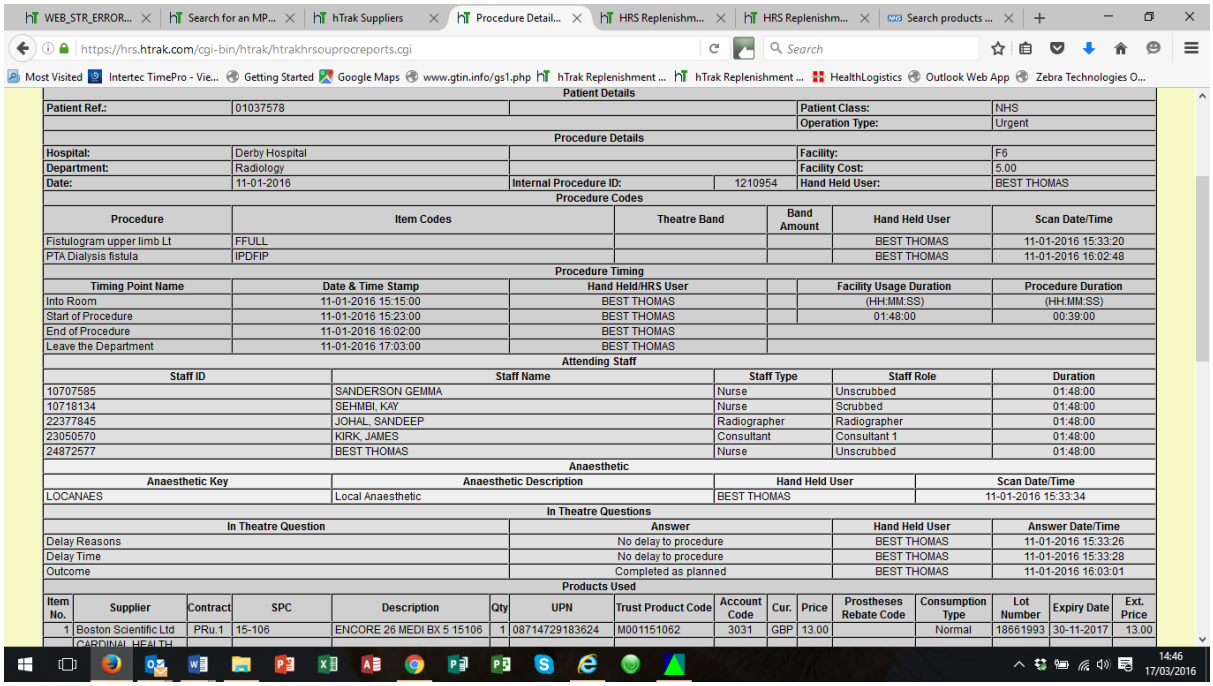
Report only for Supplier: Cook UK Ltd
Report only for SPC: ASB5-35-50-6-4

Item No.	Supplier	Contract	SPC	Description	Qty	Scanned UPN	Org. Unit	Trust Product Code	Account Code	Category	Cur.	Price	Patient Ref	Procedure Date	Health Fund	Consumption Type	Lot Number	Expiry Date	Ext. Price
1 [+]	Cook UK Ltd	PRu.1	ASB5-35-50-6-4	Advance Enforcer 35 Focal Force PTA Balloon Catheter	1		Derby Teaching Hospitals NHS Foundation Trust - Radiology				GBP	0.00	01037578	11-01-2016	NHS	Normal	6033944		0.00
2 [+]	Cook UK Ltd	PRu.1	ASB5-35-50-6-4	Advance Enforcer 35 Focal Force PTA Balloon Catheter	1		Derby Teaching Hospitals NHS Foundation Trust - Radiology				GBP	0.00	60012784	02-03-2016	NHS	Normal	6409020		0.00
Product Total(s)					2						GBP								0.00

EMAIL REPORT BACK
MENU

The screenshot shows that the product and Lot Number were used in the Trust on a procedure that took place on 11th January 2016 on Patient Ref 01037578.

8. To see more details of the procedure click the {+} to show the following information:



Patient Details

Patient Ref.:	01037578			Patient Class:	NHS
				Operation Type:	Urgent

Procedure Details

Hospital:	Derby Hospital			Facility:	F6
Department:	Radiology			Facility Cost:	5.00
Date:	11-01-2016	Internal Procedure ID:	1210954	Hand Held User:	BEST THOMAS

Procedure Codes

Procedure	Item Codes	Theatre Band	Band Amount	Hand Held User	Scan Date/Time
Fistulogram upper limb Lt	FFULL			BEST THOMAS	11-01-2016 15:33:20
PTA Dialysis fistula	IPDFIP			BEST THOMAS	11-01-2016 16:02:48

Procedure Timing

Timing Point Name	Date & Time Stamp	Hand Held/HRS User		Facility Usage Duration	Procedure Duration
Into Room	11-01-2016 15:15:00	BEST THOMAS		(HH:MM:SS)	(HH:MM:SS)
Start of Procedure	11-01-2016 15:23:00	BEST THOMAS		01:48:00	00:39:00
End of Procedure	11-01-2016 16:02:00	BEST THOMAS			
Leave the Department	11-01-2016 17:03:00	BEST THOMAS			

Attending Staff

Staff ID	Staff Name	Staff Type	Staff Role	Duration
10707585	SANDERSON GEMMA	Nurse	Unscrubbed	01:48:00
10718134	SEHMBI, KAY	Nurse	Scrubbed	01:48:00
22377845	JOHAL, SANDEEP	Radiographer	Radiographer	01:48:00
23050570	KIRK, JAMES	Consultant	Consultant 1	01:48:00
24872577	BEST THOMAS	Nurse	Unscrubbed	01:48:00

Anaesthetic

Anaesthetic Key	Anaesthetic Description	Hand Held User	Scan Date/Time
LOCANAES	Local Anaesthetic	BEST THOMAS	11-01-2016 15:33:34

In Theatre Questions

In Theatre Question	Answer	Hand Held User	Answer Date/Time
Delay Reasons	No delay to procedure	BEST THOMAS	11-01-2016 15:33:26
Delay Time	No delay to procedure	BEST THOMAS	11-01-2016 15:33:28
Outcome	Completed as planned	BEST THOMAS	11-01-2016 16:03:01

Products Used

Item No.	Supplier	Contract	SPC	Description	Qty	UPN	Trust Product Code	Account Code	Cur.	Price	Prostheses Rebate Code	Consumption Type	Lot Number	Expiry Date	Ext. Price
1	Boston Scientific Ltd	PRu.1	15-106	ENCORE 26 MEDI BX 5 15106	1	08714729183624	M001151062	3031	GBP	13.00		Normal	18661993	30-11-2017	13.00

9. Because hTrak holds only the patient reference, the patient record in Lorenzo needs to be reviewed to get the patient's contact details