

## Clinical Safety Deployment Model developed for delivery of a PCN Hub Online Consultation (eHub) approach

Clinical Safety Case Report DCB 0160 is the clinical risk management standard which NHS organisations need to comply with when they implement health IT systems. The standard is governed by [NHS England](#) and [is mandatory](#) under the Health and Social Care Act 2012. It requires a health organisation to establish a framework within which the clinical risks associated with the deployment and implementation of a new or modified health IT system are properly managed.

**You will not need a to develop a Clinical Safety Case Report DCB 0160 if you are not implementing new or modified health IT systems.**

This safety deployment model has been produced supporting the delivery of the Folkestone Hythe and Rural Online Consultation Primary Care Network (PCN) Hub (eHub) model approach and has been developed for the organisations that are responsible for the deployment of online consultation systems that have appropriately trained Clinical Safety Officers to oversee the process.

The PCN Hub (eHub) model is a centralised processing model for delivering online consultations at scale across multiple NHS GP practices. The model that the clinical safety case report is based on is specifically for use of eConsult. Others looking to work in this way, and for use of the suite of materials produced (Clinical Safety Case Report, Hazzard Log) in informing safety cases for PCNs Hub 'eHub' developments, will need to consider their own PCN Online Consultation 'eHub' model approach with their supplier on an individual basis.

The aim is to:

- Decrease the daily workflow pressures on GP Practices
- Enable patients to self-manage, self-care and refer where appropriate electronically:
- Promote the 'digital first' strategy
- Assist in the triage of demand on the practices enabling collaboration at scale
- Establish new ways of working that can improve access for patients so that they get the help that they need on the day
- Align with the Fuller report and NHS England Primary Care Recovery Plan requirements
- Exemplify many of the principles and practices that define a modern general practice approach

In this model, online consultations will be processed at a central location. Any online consultations that cannot be dealt with by the PCN Hub (eHub) clinical team, or wider PCN clinical teams, will be triaged to the patient's practice directly. The model enables effective healthcare to be delivered collaboratively with a small, dedicated team working on behalf of all the practices and contains a specialist team who are experts in triaging online consultations, so each practice only sees the requests they need to.

'Clinical safety' refers to the avoidance of harm to patients and staff as a result of technologies manufactured, implemented and used in the health service. It is important across digital systems' lifecycles and is part of a culture of patient safety focused on learning from best practice and speaking up about emerging risks. In other words, digital clinical safety is about making sure the technologies used in health and care are safe, and then using those technologies to improve patient safety.

Clinical safety in the NHS is established in statute under section 250 of the Health and Social Care Act, 2012. The process for documenting safe development and deployment of health IT systems is delineated in the Clinical Safety standards, DCB0129 for manufacturer of health technologies and DCB0160 for those deploying and using health technologies. Nationally, these two clinical safety standards outline the set of requirements to promote the effective application of clinical risk management by organisations responsible for the development, commissioning, deployment and use of health IT systems.

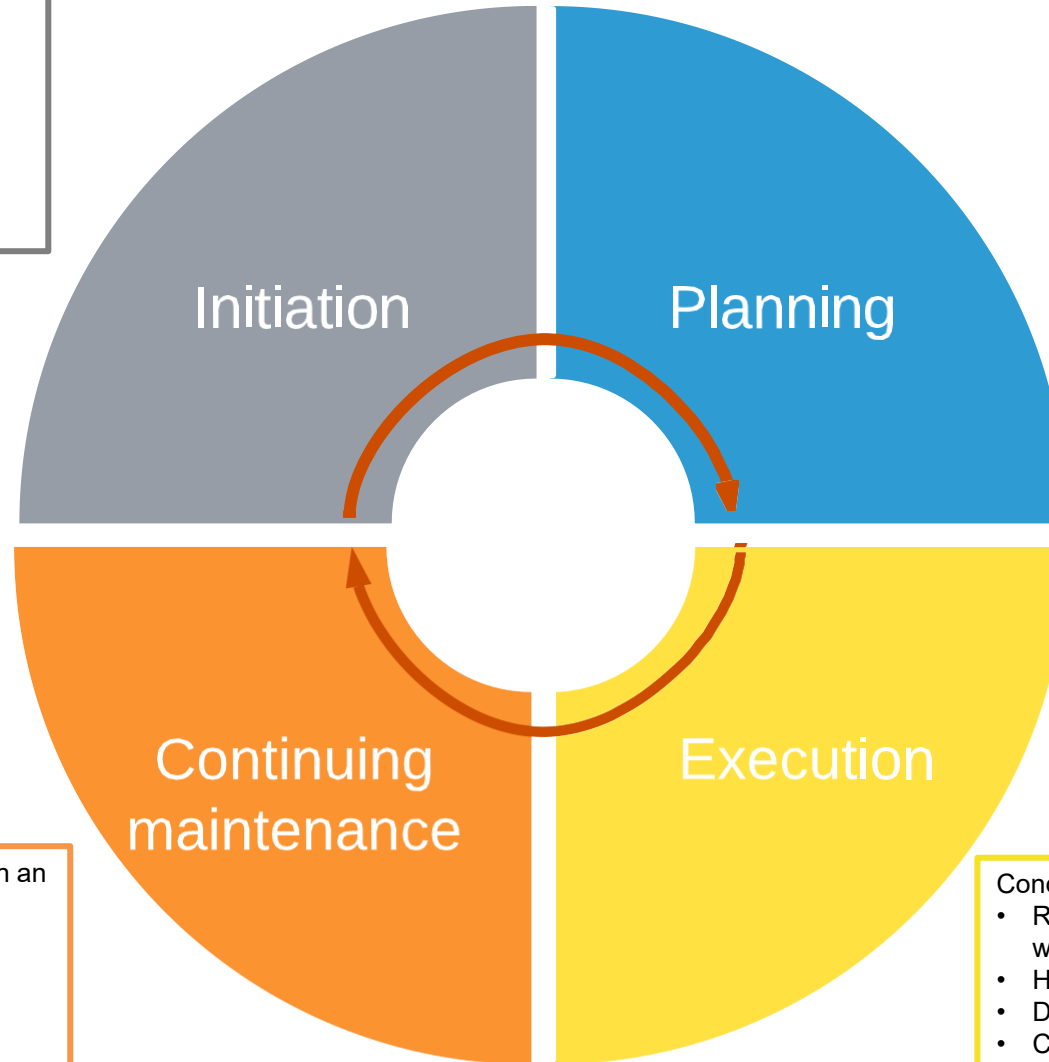
The safety deployment model provides replicable DCB 0160 Standard efficiencies and benefits while reducing enterprise risk across the scope of this PCN model deployments. It is reliant on establishing channels of communication between 'service providers', client and supplier from the shared experience of safety. The model also provides a replicable process for other client procured products and for other products types which require broad user deployments and is applicable to those PCNs wanting to work in this way.

The deployment process model has the following 'value add' facets:

- **Scalability and flexibility** - 'Localised' safety documentation can be quickly produced using the initial core safety assets replicating previous learning and with provision of a consolidated list of DCB 0160 standard requirements. This allows for large scale deployments to be managed under one model
- **Inclusivity** - The deployment process model accommodates the DCB 0160 standard safety assessment requirements for product deployment through all levels of NHS organisations (and private service providers). The model provides DCB 0160 compliance documentation which is based on straightforward safety requirements.
- **Supportive** - Critically, the Safety Deployment model is cognisant of resource limitations or time constraints and respect to service providers releasing key staff without impacting front-line care provision to patients. If not supported by such a process model, the alternative for a service provider would be of much higher impact.
- **Compliance oversight** - The model provides a core set of deployment safety requirements and allows for management of the evidencing of DCB 0160 compliance across multiple organisations.
- **Continuing improvements of Safety Assets** – The process is reliant on feedback from the service providers regarding the set up and initial use of the product, there are several identified benefits from taking this approach:
  - Set up of process to monitor additional service provider deployments.
  - Establish a continued assurance process.
  - Establishment of a support network for the creation of the core DCB 0160 standard hazard log.
  - Lessons learnt arising from the collation and dissemination of the locally generated safety documents.
  - Establishment of a 'proven' assurance support model - for example method of managing completed and partial/non-compliant 'service providers' responses and focusing support resources.
  - It is intended that the feedback loops are introduced so that further improvements and refinements can be made to the safety assets.

Additional support that has been prepared by the NHS Digital Clinical Safety team to help health and care organisations assure the clinical safety of their health IT software can be found on the [DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems](#) and [DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems](#) website as well as an [online training resource](#) to support digital clinical safety for the workforce.

- Identify strategic responsible stakeholders
- Develop an acceptable model with “local support”
- Conduct DCB 0160 safety activity
  - Primary hazard identification
  - Hazard log and hazard workshop
  - Developed core safety assets



- Engagement with local responsible organisations
- Identify and engage deploying Health Care Organisation (HCO)
- identifying communicate supporting processes and estimation of resourcing (e.g., HCO workshop attendees)
- Schedule 'local' Hazard Assessment activity
- Develop maintenance and monitoring processes

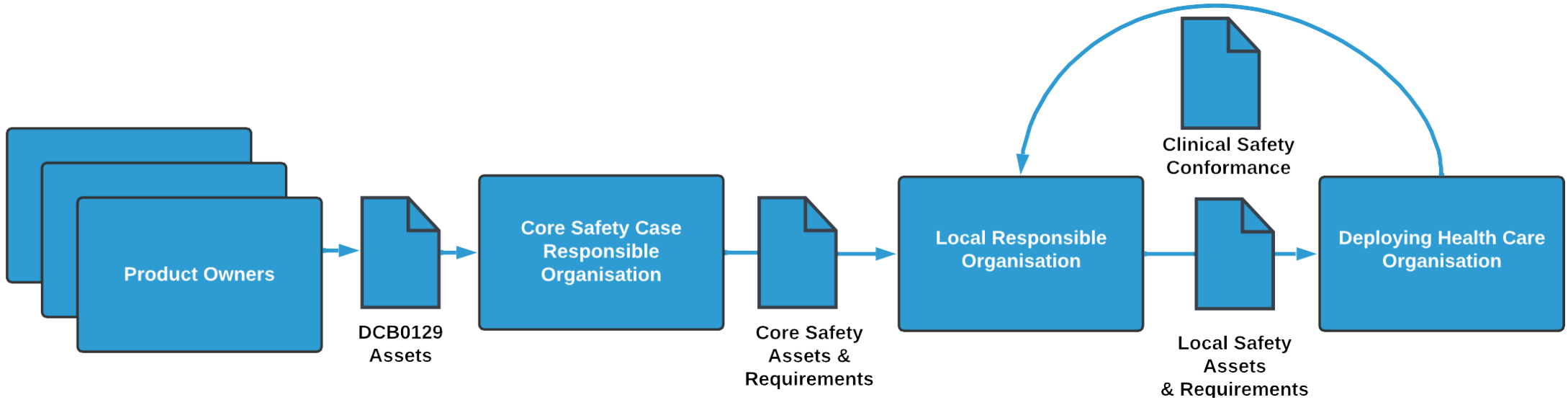
Fulfil requirements of DCB 0160 to maintain an acceptable level of compliance. This is achieved through the following 'feedback' processes and support:

- Common product development request process
- Common issues management
- Continued 'local' engagement with Core Safety Case Responsible Organisation for alignment of Safety Assets

Conduct 'local' DCB 0160 safety activity:

- Review of Core Assets against 'local' clinical workflows
- Hazard log and hazard workshop
- Develop 'Local Safety Assets'
- Continued engagement with Local Responsible Organisations, feedback assessment outcomes, additional hazards, etc.
- Develop localised certification maintenance and monitoring processes
- Adopt product issue management into local business process

### ETHOS - Safe Deployment Model Benefits



#### Product Owners (e.g., Online Consultation Provider)

Product owners are responsible for providing users with adequate support for their products use in a clinical environment including the recommendations for the following:

- Clinical intended use.
- Any recommendations identified as impacting safe use of the product.
- Point of contact in process for incident management escalation and product development clinical safety review.

#### Core Safety Case Responsible Organisation (e.g., Integrated Care Board)

An organisation or group will need to be identified for being responsible for the following key functions:

- Communication and management of the common set of safety assets.
- Distribution and management of feedback for the safety recommendations.
- Establishing process models for incident management escalation and product development clinical safety review.

#### Local Responsible Organisation (e.g., Primary Care Network or GP Federation)

A 'Local Responsible Organisation' will be responsible in the following key functions:

- Support for localised DCB 0160 safety assessment for the Deploying Health Care Organisations (HCO) using the baseline 'Core Safety Assets'.
- Support of the Deploying Health Care Organisations (HCO) continuing management of their individual DCB 160 clinical safety conformances.
- Providing a local process to support incident management and product development clinical safety review.

#### Deploying Health Care Organisation (HCO) (e.g., Constituent Primary Care Network or GP Federation Practice)

The deploying Health Care Organisation (HCO) will be responsible for the following key functions:

- Localised DCB 0160 safety assessment. This will be a DCB 0160 compliance safety assessment, or were deemed appropriate, evidence of satisfaction of the safety requirements (controls) provided by the Local Responsible Organisations.
- Continuing management of their DCB 160 Clinical Safety Conformance.
- Aligning local incident management and product development clinical safety review process with the regional model.

### Safety Model Plan

The Safety Model implementation plan can be seen as a series of project phases:

The **Initiation Phase** will typically involve the following activities:

- Identify 'Strategic' Responsible stakeholders
- Develop an acceptable model with local support
- Conduct DCB 160 safety activity
- Primary hazard identification
- Hazard login Hazard Workshop
- Develop 'Core Safety Assets'

The **Planning Phase** will outline activities and resources required to support the following:

- Engagement with Local Responsible Organisations
- Identify and engage deploying Healthcare Organisations (HCO)
- Identify and communicate supporting process and estimation of resourcing (e.g., HCO workshop attendees)
- Schedule 'local' Hazard assessment activity
- Develop maintenance and monitoring processes

The **Execution Phase** will outline activities and resources required to support the following:

- Conduct 'local' DCB 160 safety activity
- Review of Core Assets against 'local' clinical workflows
- Hazard log and Hazard Workshop
- Develop 'Local Safety Assets'
- Continued engagement with Local Responsible Organisations feedback assessment outcomes, additional hazards, etc.
- Develop localised certification maintenance and monitoring processes
- Adopt product issue management into 'local' business process

### Continued Maintenance of Certification:

Requirement of DCB 0160 to maintain an acceptable level of compliance. This is achieved through the following 'feedback' processes and support:

- Common product development and request process
- Common issue management processes
- Continued 'local' engagement with Core Safety Case Responsible Organisations for alignment of Safety Assets

#### Internal Review

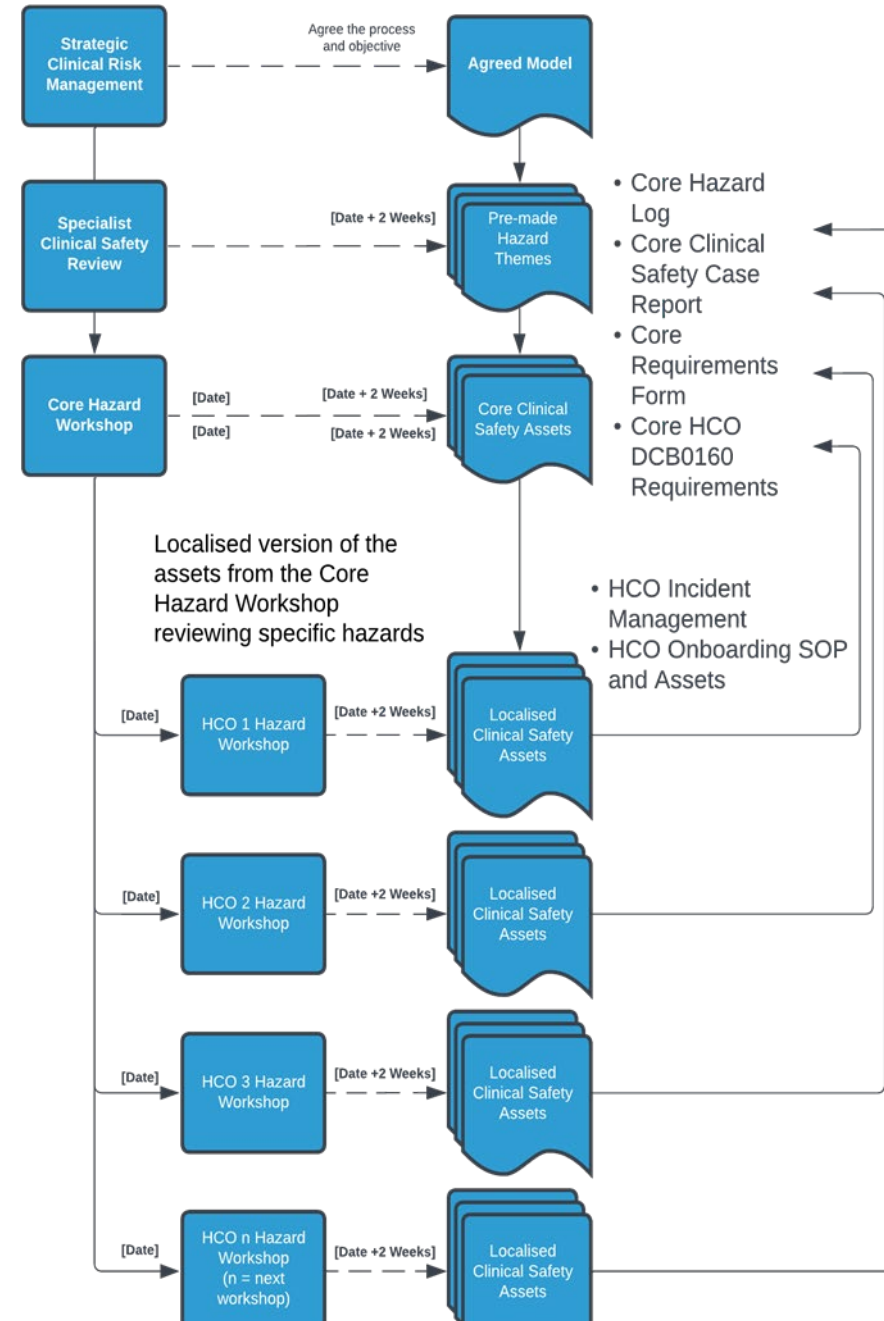
Clinical Safety Engineer  
 Clinical Safety Officer  
 EeRS Deployment Assets  
 Clinical Safety Process Expertise  
 Assessment of Product (DCB0129)

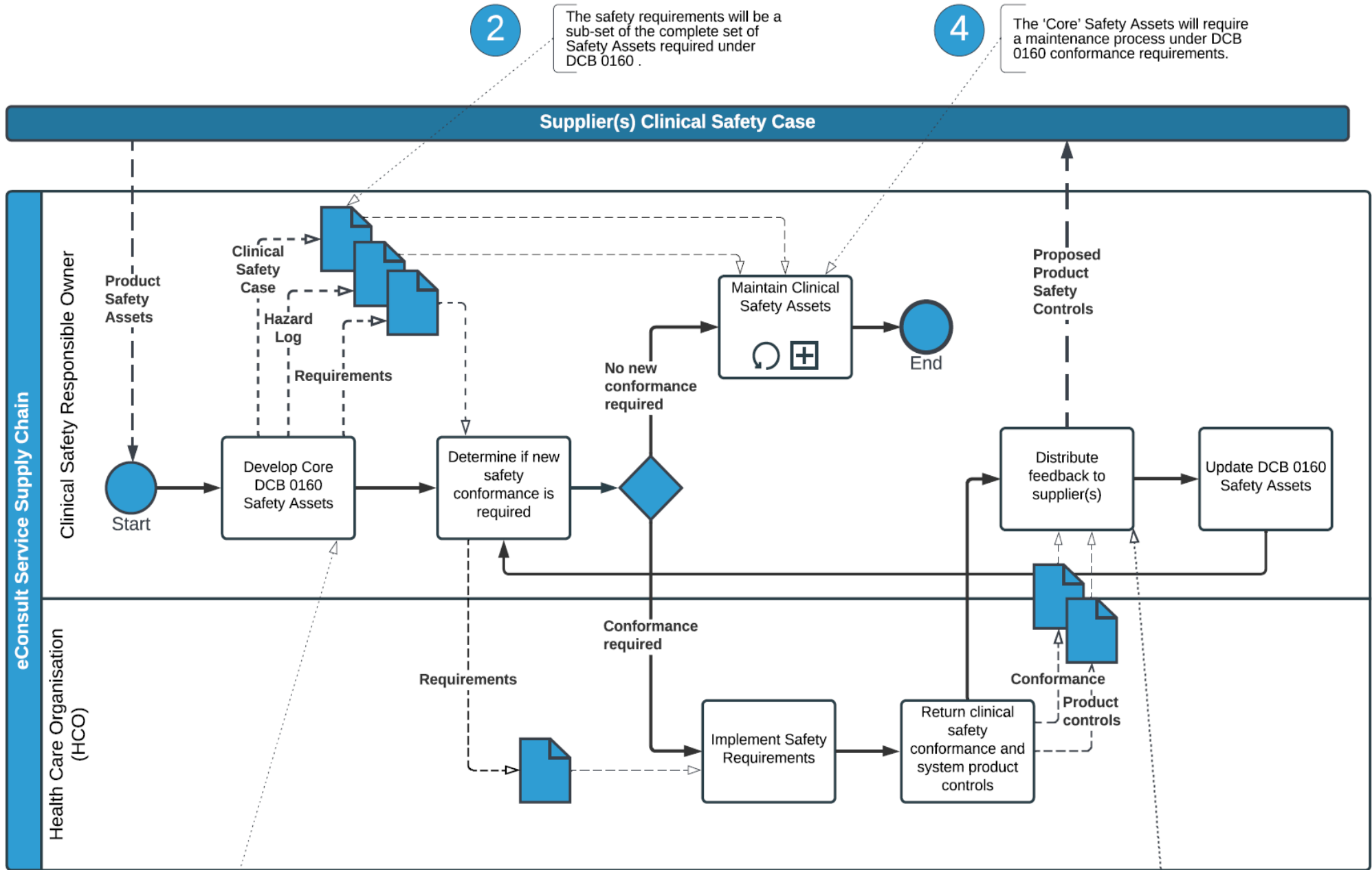
#### Core Hazard Workshop Attendees

(1+) Local user admins  
 (1+) Project / Programme Teams  
 (6+) Clinical / Medical / Care Pathway Specialists  
 (1) Product Specialist

#### HCO Workshop Attendees

(1+) Local user admins  
 (1+) Project / Programme Teams  
 (6+) Clinical / Medical / Care Pathway Specialists  
 (1) Product Specialist





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Requirements for safe use of the eHub product are provided in part from the manufacturer's safety case and also from assessment of the use of the product for clinical activities.

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Key feature of the process is providing DCB 0160 conformance inclusive of both the supplier product and Deploying organisation's needs.