How To Demonstrate Clinical Safety for Digital Health Technologies

Expert guidance from:

NHS Digital

SAFEHAND

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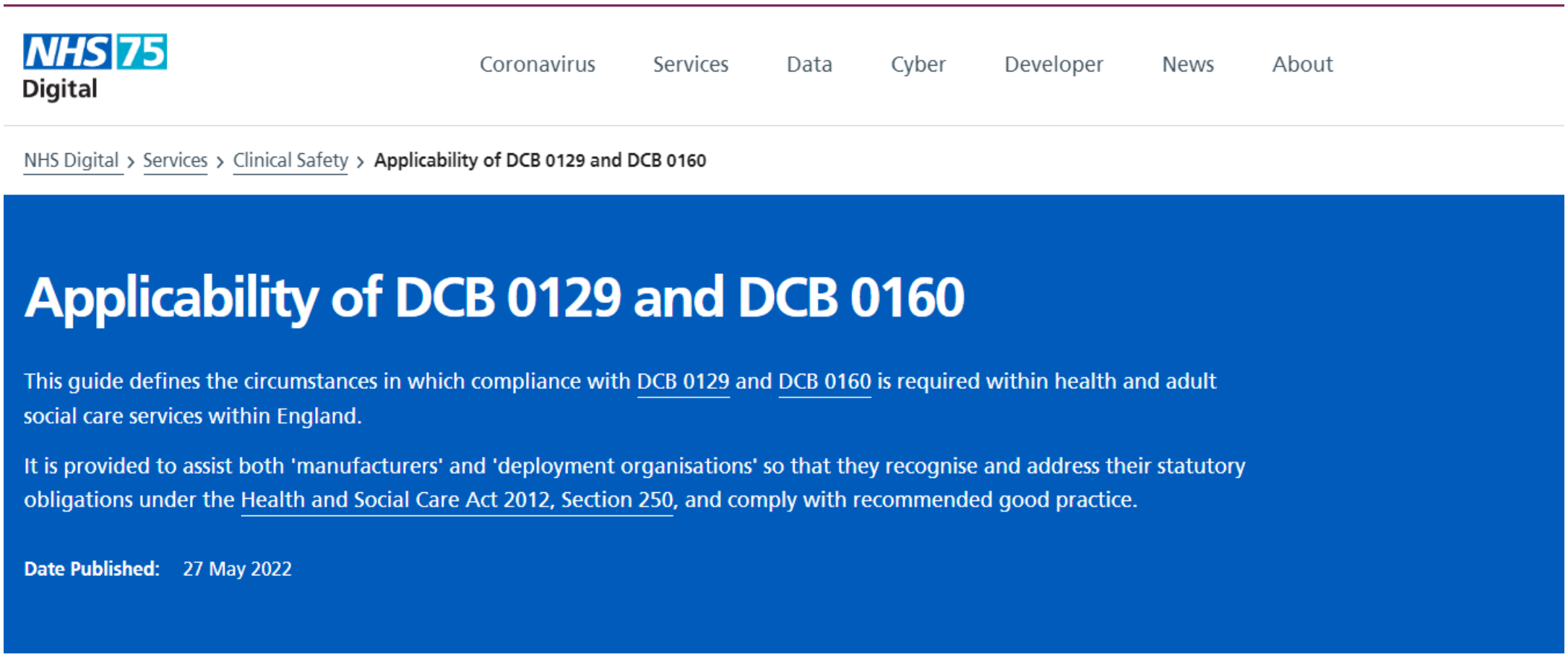
First,

Do No Harm.

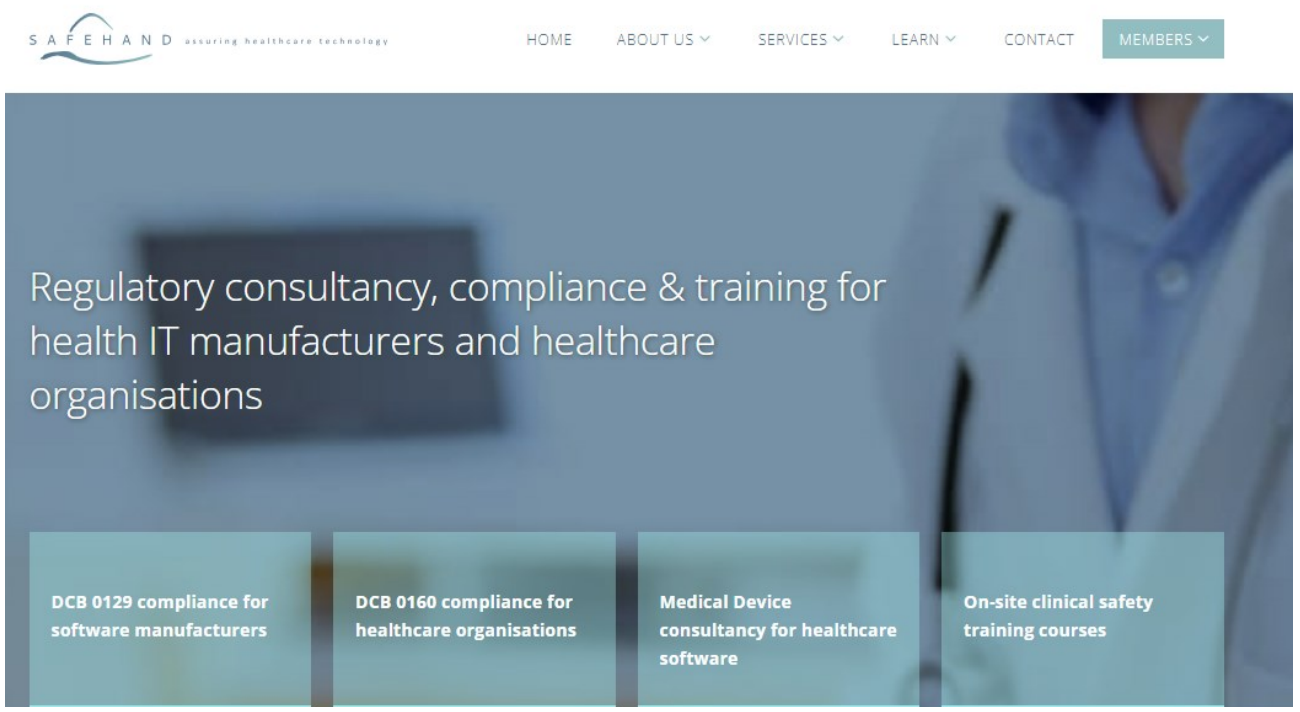
-Hippocratic Oath

This carousel is made using resources from:

1. The official NHS Digital Website



2. The amazing Safehand Website



CLINICAL SAFETY

Digital Health technologies utilised in the clinical setting can bring significant benefits, but also **carry potential risk** to patients if used in the wrong way.

As a method to mitigate these risks, NHS Digital has introduced two **MANDATORY** standards which all digital product manufacturers have to comply with in order to sell into NHS England.

These 2 important standards are:

DCB 0129 DCB 0160

DCB 0129

is the clinical risk management standard which **manufacturers of health IT systems and apps** need to comply with.

DCB 0160

is the clinical risk management standard which **NHS organisations need to comply with** when they implement health IT systems.

Both are governed by **NHS Digital** and is a **mandatory requirement** in England.

WHAT DOES THIS APPLY TO?

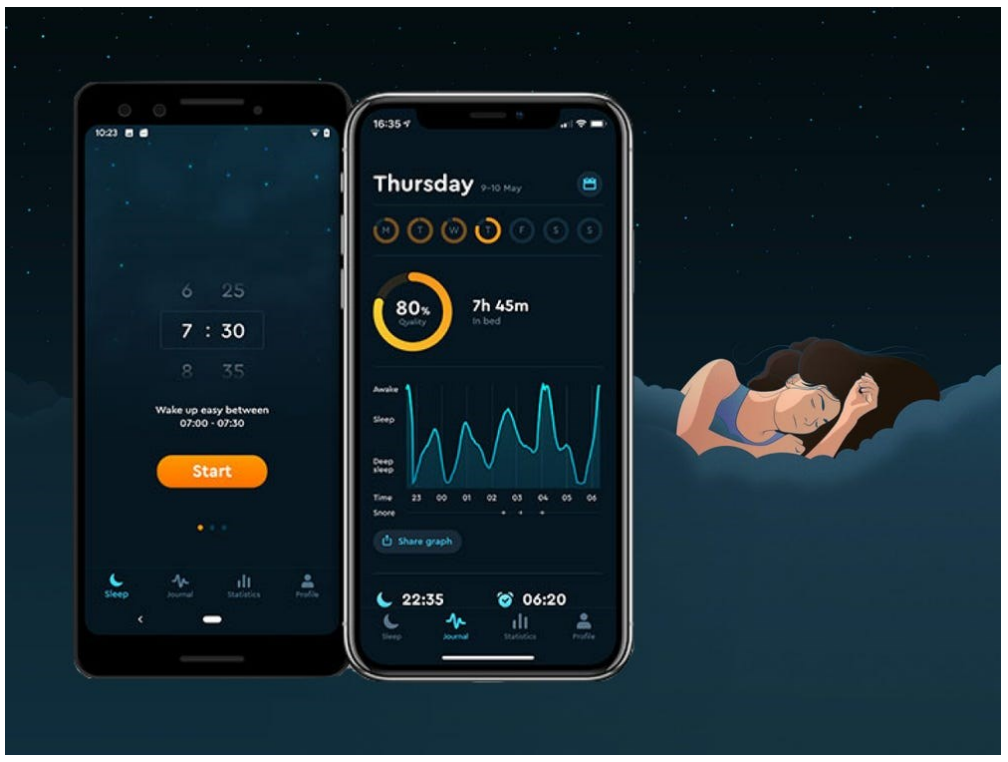
The **DCB 0129 applies** if your product:

1. Is developed/deployed and is publicly funded for use in England,
2. Support health and/or **adult social care services** in England,
3. Influence, support, manage the real-time or near -real-time direct care of patients/service users,
4. Is placed on the market as a 'Medical device' or an accessory to,
5. Is implemented within a Health IT system,
6. Is integrated within a Health IT infrastructure.

In short, if a digital product can influence **healthcare delivery** then DCB 0129 applies.

WHAT DOES IT NOT APPLY TO

Strictly speaking, apps which only provide **general wellness advice** or **monitor fitness** do not need to comply.



Similarly, apps which **provide simple information** in essentially the form of an electronic textbook are not within scope.

DCB 0129 DECISION TREE

Pro Tip:

The SAFEHAND website contains a very **helpful decision tree** that can help you determine if your HealthTech product requires **DCB 0129**.

DCB 0129/0160 Compliance Decision Tree

Welcome to our DCB 0129/0160 compliance decision tree.

Answer the questions below and we will guide you on whether your product is likely to require assurance under DCB 0129/0160. Note that the information provided is guidance only and the result does not constitute a formal decision nor is it in any way legal advice. We would advise that you contact us to discuss your product in more detail and we can then provide specific recommendations on how you should proceed.

DCB 0129/0160 Decision Tree

Is the product used only for research purposes?

(For a product to be a research tool only, it must not influence the care of individuals. Instead it will produce statistical information to support a hypothesis.)

YES

NO

ONE IMPORTANT CAVEAT

While personal wellbeing and fitness apps do not need to comply, there is often **a very thin line** to tip toe across.

If your product is designed for or **targets a specific medical condition** or could in any way **cause harm** to the consumer, you are likely to need to comply.

If you are unsure, consult an expert.

DCB 0129

To comply with the standard, manufacturers needs to undertake a formal risk assessment on the product and produce **three documents** summarising the outcome:

Clinical Risk Management Plan

Hazard Log

Clinical Safety Case Report.

Note that DCB 0129 is **supplemental** to the requirements of the NHS Information Governance Toolkit and the Medical Device Directive/Regulation.

CLINICAL RISK MANAGEMENT PLAN

A document which sets out at the start of a project **what you are going to do** to safely assure the product.

The plan makes sure that the project is organised, **agrees up front the intentions** and level of rigour and allows you to know when you have completed the exercise.

The purpose is to allow all the stakeholders know what they should be doing and to give them the **opportunity to validate and potentially challenge** the approach to the assessment.

HAZARD LOG

This is essentially a structured document which sets out the **potential scenarios (hazards)** that could lead to harm.

For each hazard you'll decide on the **severity and likelihood** of it causing harm and bring those two elements together to estimate the level of clinical risk.

It includes **the impact the hazard might have** on the patient and the controls that've been put in place to prevent the scenario from arising.

It explains **how harm could theoretically arise** but, in practice, probably won't because of the controls that've been put in place to **mitigate the risk**.

CLINICAL SAFETY CASE REPORT

The safety case consists of **three key elements**.

A **set of claims** regarding the safety position of the product, **evidence** to back up those claims and **argument** – the narrative glue to bring everything together.

The safety case would **bring all this together** to support the claim that this part of the system was acceptably safe.

It is essential to **set out clearly the evidence** that a safety argument is valid and **not simply try and pass the risk on** to other parties.

DCB 0129 VS DCB 0160

Essentially,

- **DCB 0129** applies to the manufacturer of the health IT system.
- **DCB 0160** applies to the healthcare organisations implementing it.

NHS Digital requires that both pieces of work are conducted. Both require a Clinical Safety Officer to oversee the process.

The two standards are very similar in what is required so essentially both the supplier and healthcare organisation are **doing the same piece of work from** two different perspectives.

CLINICAL SAFETY OFFICER

The CSO **must be a clinician** who is currently registered with a professional body. Typically, this might be a doctor, nurse, pharmacist, etc.

They must also be competent to undertake the **clinical risk management task**. In practice this means that they should have received appropriate training.

The clinician should also ideally **be familiar with the clinical domain** that the system relates to.

ROLE OF A CSO

Both DCB 0129 and DCB 0160 require that a CSO is appointed to:

. Undertake/oversee the project,

. Define and document a safety assurance process, carry out a structured risk assessment on the product,

. Issue three documents summarising the assessment

. Sign-off the deliverables once they have been created.

. Continue to manage clinical risk during live service.

HOW TO BE A CSO

Besides being a professionally registered clinician, there are specific training delivered by NHS Digital AND Safehand that can help start you off the right track.

NHS 75 Digital

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NHS Digital › Services › Clinical Safety › **Clinical Risk Management training**

Digital Clinical Safety training

Digital Clinical Safety training is designed to provide NHS organisations and manufacturers of health IT products with training in the principles of safety, risk management and risk mitigation.

SAFEHAND assuring healthcare technology

HOME ABOUT US SERVICES LEARN CONTACT MEMBERS

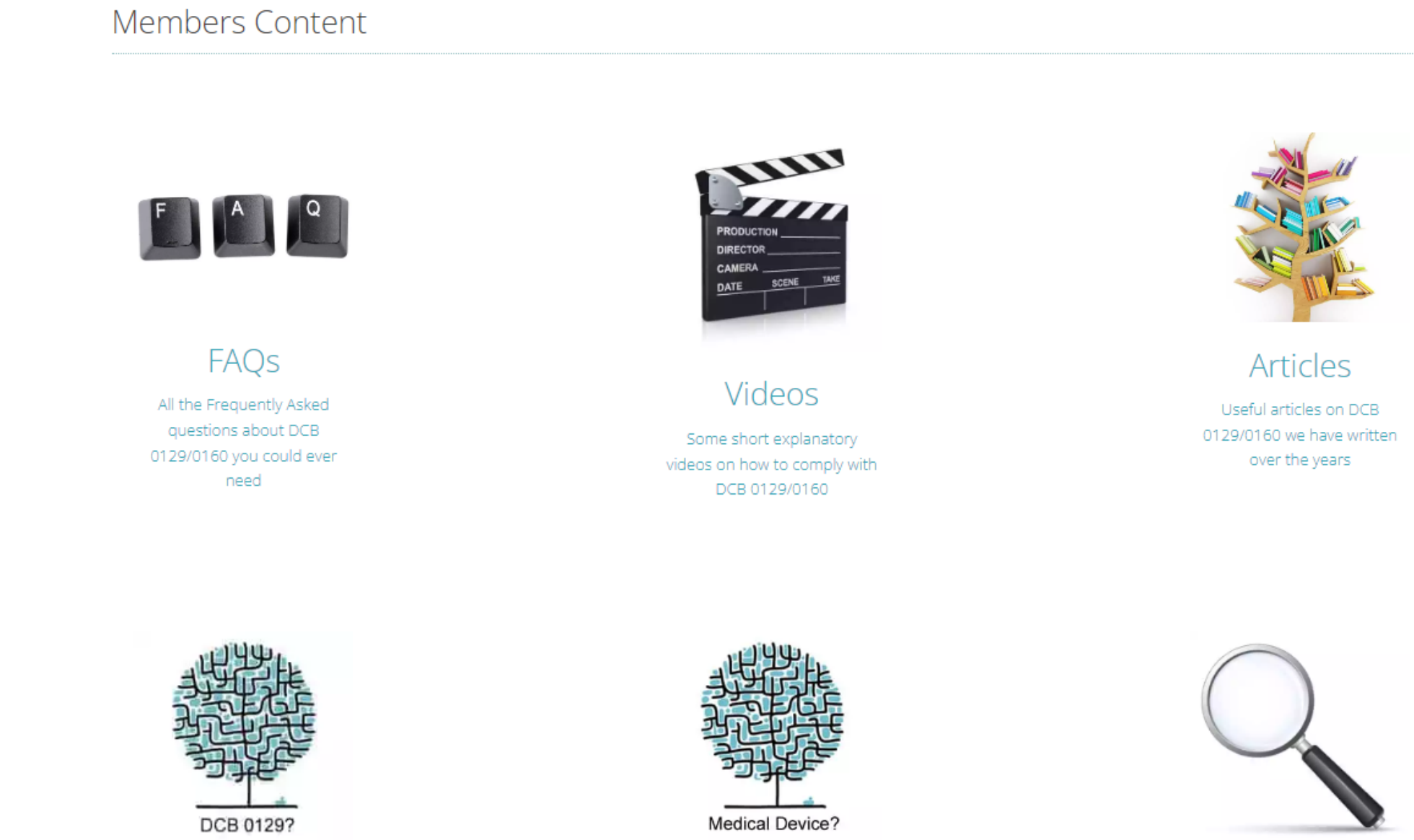
Clinical Safety Training Courses

Clinical Risk Management training with Safehand

Safehand provides NHS organisations with training for Clinical Safety Officers and the entire project team. Learn the detailed techniques of proactive clinical risk management and DCB 0129 / DCB 0160 compliance.

IMPORTANT TIP.

To access more in-depth, authoritative resources about the DCB 0129/DCB 0160 - join the **FREE** members area of Safehand that has TONS of easy to understand material.



Hope you found this helpful!

This is a series we are making to help HealthTech Innovators access better resources.

Just our small way of helping!