

Ref. No: 1525  
Date: 02/05/25  
Subject: Clinical Safety of Health IT Systems

## REQUEST

I am writing to request information under the Freedom of Information Act 2000 regarding the use of Health IT Systems in your organisation.

For the purposes of this FOI, Health IT Systems are defined as “[a] Product used to provide electronic information for health or social care purposes. The product may be hardware, software or a combination.”

Please note that this definition encompasses any hardware or software product used within the organisation. It does not have to be used for a clinical purpose (i.e., it may be clerical) and applies to both non-medical and medical devices (the latter as defined by UKMDR2002).

This definition is taken from the following sources:

- [DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems - NHS England Digital](#)
- [DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems - NHS England Digital](#)

### Requested Information:

1. The **total number of Health IT systems** currently in use by the organisation.
2. The number of Health IT systems currently in use by the Trust that have **BOTH DCB0129 (from the manufacturer) AND DCB0160 (from the deploying organisation) Clinical Safety Case Reports**.
3. The number of Health IT systems currently in use by the Trust that **have a valid DCB0129 Clinical Safety Case Report from the manufacturer ONLY** (i.e. have a DCB0129 report but NOT a DCB0160 report).
4. The number of Health IT systems currently in use by the Trust that **have a valid DCB0160 Clinical Safety Case Report from the deploying organisation ONLY** (i.e. have a DCB0160 report but NOT a DCB0129 report from the manufacturer).

5. The **total Whole Time Equivalent (WTE) of Clinical Safety Officers** who are currently actively working on DCB0129/DCB0160 implementation within the Trust.

## RESPONSE

1. The **total number of Health IT systems** currently in use by the organisation.  
**138**
2. The number of Health IT systems currently in use by the Trust that have **BOTH DCB0129 (from the manufacturer) AND DCB0160 (from the deploying organisation) Clinical Safety Case Reports**.  
**60**
3. The number of Health IT systems currently in use by the Trust that **have a valid DCB0129 Clinical Safety Case Report from the manufacturer ONLY** (i.e. have a DCB0129 report but NOT a DCB0160 report).  
**None - we would request the 0129 to allow us to complete the 0160, so we would not have one without the other**
4. The number of Health IT systems currently in use by the Trust that **have a valid DCB0160 Clinical Safety Case Report from the deploying organisation ONLY** (i.e. have a DCB0160 report but NOT a DCB0129 report from the manufacturer).  
**None - Our Policy is we need the 0129 to allow us to complete the 0160, so as above we wouldn't have one without the other.**
5. The **total Whole Time Equivalent (WTE) of Clinical Safety Officers** who are currently actively working on DCB0129/DCB0160 implementation within the Trust.  
**1.8 WTE**