

Medical Devices Committee – Risk Report



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1.0 Purpose

This guidance describes how to run the key risk reports for the NHS Lothian (NHSL) Medical Devices Committee and the key access to Datix required for the relevant individuals to be able to run these reports.

2.0 Scope

Senior members of the Medical Devices Committee including staff from Medical Physics and Consultant Clinicians who need access to Datix in order to do the work of the Medical Devices Committee.

3.0 Definitions

Datix is the electronic risk management system used by NHS Lothian.

The Adverse Event module holds all adverse events logged in the system by staff reporting incidents across NHS Lothian.

An Adverse Event report is a filtered report to select adverse events that are of interest to the Medical Devices Committee.

The Risk Register is a module where services identify and record risks relating to their service. The risks on the Risk Register are owned by the respective service.

A Risk Register report is a report filtered to select risks on the risk register that are of interest to the Medical Devices Committee.

MDC – Medical Devices Committee

CMG – Clinical Management Group, Acute Services

SaMD – Software as a medical device

Off-label use of a *medical device* involves use for a medical purpose that is out with its intended use as determined by the manufacturer. This includes: using a *medical device* with paediatric patients when the manufacturer states that the intended purpose is for use with adults only; using an accessory that is different to the accessory specified by the manufacturer; using a *medical device* for an alternative medical purpose; using a product for a medical purpose that is not a medical device.

4.0 Roles and responsibilities

4.1 The Chair of the Medical Devices Committee

The Chair of the Medical Devices Committee should have access to the Adverse Event and Risk Register modules in Datix relating to medical devices and equipment and know which

committee members require the same access to do the work of the Medical Devices Committee. The running of the reports may be delegated to an identified individual.

The Chair will escalate issues as required to CMG or equivalent. The Chair can provide advice to services, as required, relating to medical device risk evaluation and management.

4.2 Medical Devices Committee Clinicians

Clinicians representing hospitals or clinical areas should have access to the Adverse Event modules relating to medical devices and equipment and if relevant, to the Risk Register modules in Datix relating to medical devices and equipment. This is particularly pertinent when leading equipment replacement programmes.

4.3 Medical Devices Committee Medical Physics Staff

The Head of Medical Physics, Head of Medical Equipment Management and Clinical Engineering, the East and West Sector Managers should have access to the Adverse Event and Risk Register modules in Datix relating to medical devices and equipment.

5.0 Main content and evidence base

5.1 Datix Access Request Form

The Datix Support web page on the intranet has useful information including the Datix Access Request Form. [Datix Support \(scot.nhs.uk\)](https://scot.nhs.uk)

The Datix Access Request Form should be filled in and signed by your line manager. Check you have the correct access across all NHS Lothian Divisions. If you don't then contact Datix Help on the NHS Lothian email distribution list. datixhelp@nhslothian.scot.nhs.uk

If you already have access to Datix your access can be changed by emailing Datix Help on datixhelp@nhslothian.scot.nhs.uk

5.1.1 Required Datix access: Adverse Events

Ask for access to all Adverse Events in the **Category of Medical Devices and Equipment** for all Divisions of NHS Lothian including the four Health and Social Care Partnerships (HSCP) and that this is for Medical Devices Committee work.

5.1.2 Required Datix access: Risk Register

Ask for access to all Risks on the Risk Register for all Divisions of NHS Lothian including the four HSCPs where the answer to the following two questions is **Yes**. You want to see both open and closed risks.

Does this risk relate to a medical device/equipment/consumable and therefore be visible to the NHS Lothian Wide Medical Device Committee

Does this risk relate to OFF Label use of a Medical Device/Software as a Medical Device not licensed to a high enough Class (Select Yes if Unsure)

The second question is a subset of the of the first but the intention is to capture some risks that staff may not have told us about so the answer could be **No** to the first question and **Yes** to the second.

5.2 Running an Adverse Event Report for MDC

Select **Adverse Events** and Click on **New Search**.

A blank Datix Form comes up, type in @prompt in the **Reported Date** box as shown below.

Scroll down to the bottom of the page to the **Main Category** section and select **Medical Devices and Equipment** from the scroll down menu. The **Main Category** box will show MEDDEV as shown below. Then press Search at the bottom of the Page.

A date range will be shown, so select the date range using the calendars.

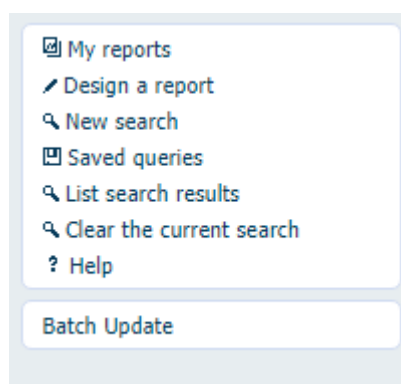
ther information. Please complete the fields below and press Continue:

from: to:

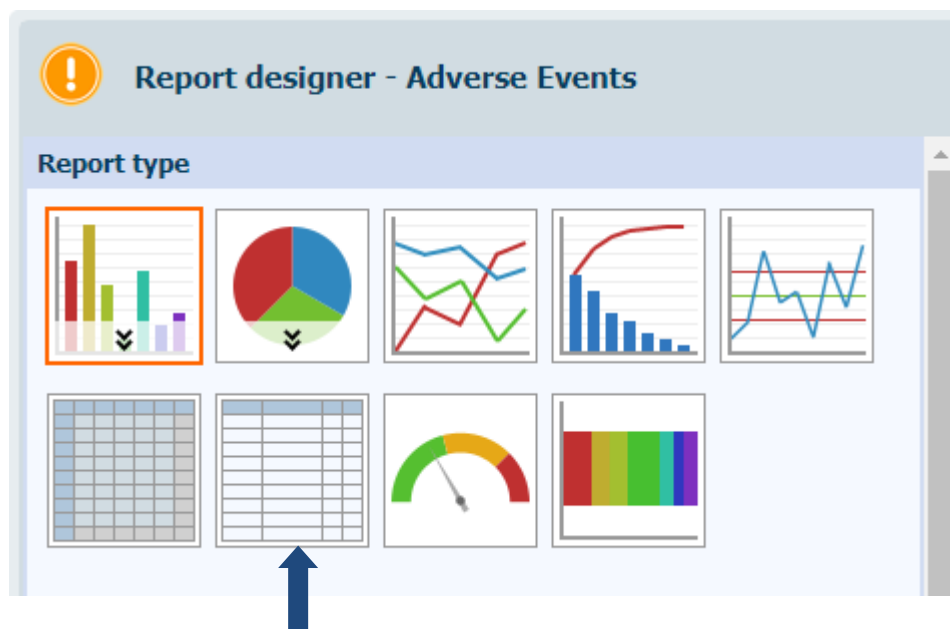
Then press **Continue**.

A list of Medical Devices and Equipment Adverse Events will come up. I cannot show this as it is confidential information.

On the left hand side of the screen there is a box, shown below.



Select **Design a report**



Select the listing report indicated by the arrow by clicking on the box.

The screenshot shows a web-based report configuration interface. At the top, there are four icons: a grid, a table, a gauge, and a bar chart. Below these is the 'Report settings' section. It contains three main fields: 'Custom title' with the value 'MDC Adverse Event Report', 'Query' with the value '[Current criteria]', and 'Base listing report' with the value 'Adverse Events - ID/Dept/Situation/Severity/Summary of Review/Lessons'. Below these is a 'Filters' section, which is expanded to show 'Reported' dates from '06/07/2022' to '31/08/2022'. At the bottom of the interface are three buttons: 'Run report', 'Export', and 'Clear settings'.

The listing box is highlighted in red. Then type in the name of your report into the **Custom title** box.

Leave the **Query** as current criteria.

Scroll down the range of base listing reports until you get to:

Adverse Events - ID/Dept/Situation/Severity/Summary of Review/Lessons Learned

Select that. It is currently about 15 down in the list. You may prefer another option but this report gives enough information for the MDC including the ID number, summary of review and lessons learned.

Select **Run Report** and you will see your report on the screen.

You can **Export** the report from the box above or from the bottom of the report.

A box comes up offering a PDF or Excel Report. Excel usually works best. The report will then appear as a download on your computer.

You can ask Datix Help to save a report for you but the list of My Reports is longer than the list of base listing reports.


5.3 Running a Risk Register Report for MDC

Select Risk Register by clicking on the writing and you will see this screen. Usually only risks with final approval will have a number next to them.

Select **new search** and a blank Risk Register form comes up, as shown below. Select **Yes** to the **...visible to the MDC** question illustrated below.

Risk Description	
ID	<input type="text"/>
Title	<input type="text"/>
<p>Risk Description</p> <p>When deciding the risk description, consider the following approach:</p> <p>"There is a risk that..." What event could happen that creates uncertainty as to the achievement of the stated objectives?</p> <p>"because..." Why and/or how could this event occur?</p> <p>"leading to..." What would the consequence be if the event occurred?</p>	<input type="text"/>
Does this risk relate to a medical device/equipment/consumable and therefore be visible to the NHS Lothian Wide Medical Device Committee	<input type="text" value="Y"/>
Does this risk relate to OFF Label use of a Medical Device/Software as a Medical Device not licensed to a high enough Class (Select Yes if Unsure)	<input type="text"/>
Controls in place	<input type="text"/>

Scroll to the bottom of the screen to the Key Dates section.









Key Dates	
Date Opened Date risk identified	<input type="text"/>
Date risk reviewed (dd/MM/yyyy) Change this date each time you review the risk	<input type="text"/>
Next review date (dd/MM/yyyy) Date when risk is due for review	<input type="text"/>
Date Risk Closed (dd/MM/yyyy)  This field is only to be completed by Risk Owner named above	= <input type="text"/>

If you place a single equals sign in the **Date Risk Closed** box you will only capture open risks. This is the report we want for MDC.

If you place nothing in the box you capture both open and closed risks. You might want to do this if you are searching for a risk that the clinical service has closed meantime.

If you want to search for closed risks only then put == in the box. (Two equals signs side by side).

Select **Design a report**

- + Add a new risk
-  Assurance Framework
-  My reports
-  Design a report
-  New search
-  Saved queries
-  List search results
-  Clear the current search
-  Help

Batch Update



Select the listing report as shown by the arrow by clicking on the box.

Report settings

Custom title

* Query

* Base listing report

Select the following as the base listing report.

Risk ID/Level/Division/Mgt/Service/Title/Description/Rate/Level/Opened/Reviewed

Select **Run Report** to get the report on screen. Select **Export** to take you to a box where you can choose PDF or Excel. Excel works best. Select **Export** in the box and your report is downloaded to your NHSL computer.

You can choose other reports.

5.4 Running an OFF Label/SaMD Report for MDC

Select **Yes** to the second question relating to **OFF Label/SaMD** as illustrated below and follow exactly the same process as described in section 5.3. The same rules apply for selecting open, closed or all risks by using the equals sign in the **Date Risk Closed** box.

Does this risk relate to a medical device/equipment/consumable and therefore be visible to the NHS Lothian Wide Medical Device Committee	<input type="text"/>
Does this risk relate to OFF Label use of a Medical Device/Software as a Medical Device not licensed to a high enough Class (Select Yes if Unsure)	<input type="text" value="Y"/>
Controls in place ?	<input type="text"/>

5.5 Searching for an Open Risk on the Risk Register

5.5.1 The ID of the Risk is known

If you know the ID of the Risk Register then select new search and put the ID number into the search box. Then scroll to the bottom of the screen to press search.

Risk Description	
ID	<input type="text"/>
Title	<input type="text"/>
Risk Description	<input type="text"/>

5.5.2 The ID of the Risk is not known

Run the Risk Register Report as described in section 5.3. The Risk will usually be open so run the report using the open risk criteria. The risks will come up on your screen and you can scroll through them to find the one you want. You stop short of the Design a Report section.

5.6 Feedback/Communication within Datix

Select the incident from the report by clicking on the ID number or search for the incident using the search function and putting the ID number in the ID field. On the top left hand side select **Feedback/Communication** by clicking on the words.

Name and reference

Review

Feedback/Communication

People Involved

Notepad

Attach Documents

This takes you to the following screen.

All users
Only users with e-mail addresses are shown.

Additional recipients
Enter e-mail addresses of other recipients not listed above. You can enter multiple addresses, separated by commas.

Message

Subject DatixWeb feedback message

Body of message This is a feedback message from Your, Name. Adverse Event reference is *****. The feedback is:

You can select email addresses of staff that have access to Datix from the **All Users** drop down menu. You can also type in other users email addresses longhand in the **Additional Recipients** box. Type your message in the **Body of Message** box. You can add attachments if you wish. Press send. You will be asked if you want to send and save. Click this. Save the record at the bottom of the page. Your message will be recorded in the section where this example says **No messages**.

Attachments

Send message

Message history

Date/Time	Sender	Recipient
No messages		

The Feedback Communication function is available in the Adverse Event Module and the Risk Register Module.

5.7 Using the Notepad Function within Datix

The notepad function can be selected from the same menu in the Adverse Event Module.

In the Risk Register module the notepad is part of the Risk Register document which becomes visible once you are in the individual Risk on the Risk Register.

Notepad	
When the risk is reviewed please provide the date and a summary of changes here.	

If the risk has been discussed at MDC and there has been an action by MDC such as escalation of the risk to a committee or person with a key NHSL role then this can be recorded here. The Risk Owner and Risk Handler should be informed and it is sensible to annotate the entry as On Behalf of the Medical Devices Committee. This would usually be done by the MDC Chair.

5.8 Adverse Event and Risk Ownership

The Adverse Events and Risks on the Risk Register are owned by the relevant service and it is their responsibility to manage them and their responsibility to close them when it is appropriate to do so.

Communication from Medical Physics staff and from the Medical Devices Committee is usually gratefully received.

5.9 Datix Training

NHSL run Datix training courses which are well worth doing.

6.0 Associated materials

[Adverse Event Management Policy](#)

[Adverse Event Management Procedure](#)

[Medical Devices Policy \(nhslothian.scot\)](#)

[Datix Support \(scot.nhs.uk\)](#)

7.0 Stakeholder consultation

Key members of the Medical Devices Committee

8.0 Monitoring and review

This guidance will be changed as necessary if the report requirements change.