Quality resources

CAPA (Corrective And Preventative Actions)

Contents

1. Basic overview

The CAPA database has two main functions:

1. It allows users to submit Corrective or Preventative actions

2. It allows those actions to be reviewed.

Details for how to submit corrective and preventative actions are detailed on the 'how to' tab of the database. The information from those submissions are saved into the database for review.
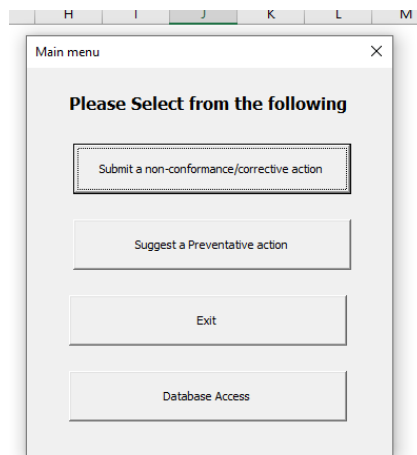
This guide will focus on how to set up the database and how to use it to review submitted CAPA's.

2. How to use the CAPA database

When first opening the database you will need to enable macros:
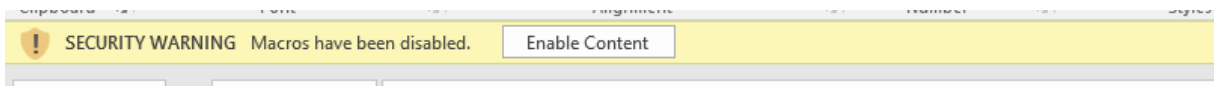
You will then see a menu pop-up. You will need to select the 'Database access' option.

The default password is 'Noncon', this password can be changed on the 'Math' tab, cell J1. Please note that the password is case sensitive. The password is the same for the example version.

Before you can properly use the database you will need to set up certain lists. The first of these can be found on the 'Lists' tab & are highlighted blue.

In column A you will find 'Category'. This list is used to identify how you will categorise your CAPA's. When users submit a CAPA they will select from this list. When you populate this list it will change the database throughout. There are example categories in place to help get you started.

Shareable QR – CAPA		Version 1	
ID NA	Implemented 30/5/2024	Review 30/5/2028	Page 2 of **15**

	A	
1	**Category**	
2	*Access, Admission, Discharge and Transfer issue*	
3	*Collision/Struck against moving or stationary object*	
4	*Communication failure Consent*	
5	*Delay / failure to treatment or procedure*	
6	*Diagnosis, Scans, Tests and procedures (clinical)*	
7	*Documentation and Health Records*	
8	*Environmental / Infrastructure / Equipment*	
9	*Medical Devices (Clinical)*	
10	*Infection Control*	
11	*Information Governance*	
12	*Information Technology*	
13	*Manual Handling*	
14	*Patient Care*	
15	*Security*	
16	*Staffing*	
17	*Unsure - please detail*	

In Column E you will find 'area', this is to detail any specific parts of your service – e.g. Clinical or admin. When entered in here they will star to appear throughout the database.

E	Out
Area	
	Acc
Clinical	Rej
Admin	N/A
	Ple

Column G can be used to detail themes used when reviewing CAPA's. This is currently populated with some which have been used previously but can be changed as needed.

After this you can also alter the timings for how long there is for a corrective or preventative actions review to start. These are altered on the 'KPI' tab. There you will find something called 'timings'. Changes here will cascade throughout the sheet.

Timings - as days	
Days until corrective overdue	28
Days until preventatice overdue	84

Change as appropriate

The final part of the setup is to fill in the documents list found on the 'docs' tab. This is to list any local documentation used throughout your service. These are shown in the submission windows for both corrective and preventative actions.

|	Document	Total corrective	Total preventative
23	Guidance - Booking an Interpreter & Chaperone provision	0	0
24	Guidance - BPPV in VM clinics	0	0
25	Guidance - Checking the work	0	0
26	Guidance - Clinic Preparation	1	0
27	Guidance - Complex Auditory Patient Appointment	1	0
28	Guidance - Complex Diagnostics	0	0
29	Guidance - Deceased or Voluntary return of hearing aids	0	0

With these steps completed the database is ready for use.

CAPA submissions can be reviewed one of two ways, either manually directly into the 'CAPA DB' tab or using the review window. This guide will cover both. A worked version of the database can be found within these resources.

3.   Using the review window

It is recommended you use the review window as it auto-completes several fields that would otherwise require manual update.
To access the review screen, click one of the 'Click to open review screen' buttons on the CAPA DB tab (found in column R) – please note this is after going into admin access from the initial menu
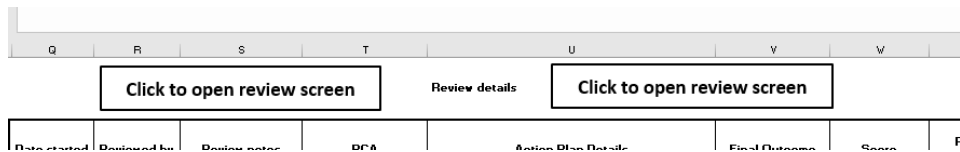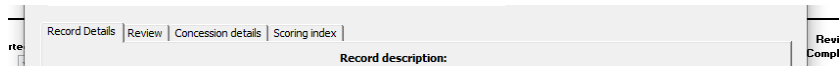
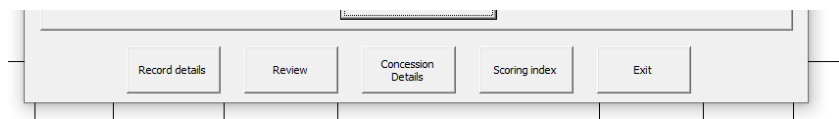When you open the window, the following screen will appear:
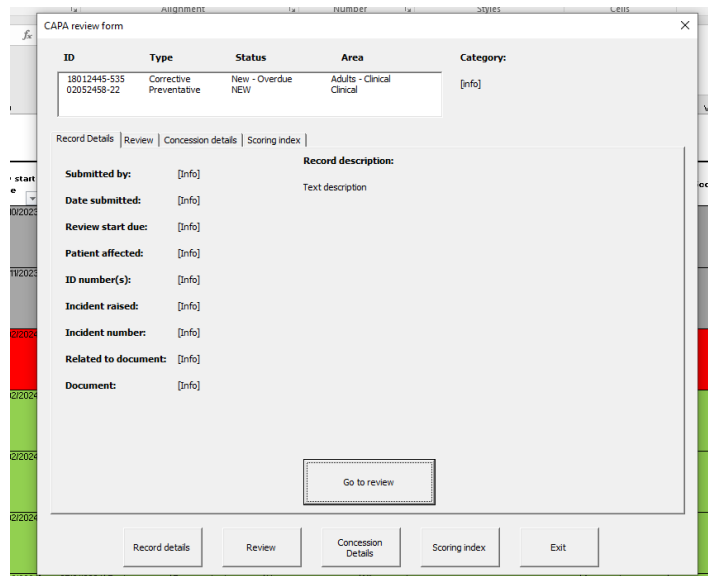
General navigation –

This screen can be navigated through tabs shown below the selection window

Or through buttons on the bottom.

View records – returns to the view record screen

Review – goes to the review screen

Concession details – goes to the concession screen

Scoring index – shown in this guide but not included in the template. This is in case you use a different scoring system. Please note the scoring index tab can be changed as needed.

Exit (buttons only) – closes the window.

View record details -

All Actions which are currently 'New' or 'Under review' will appear in the window towards the top left. These are organised by date, going oldest first. You will see the CAPA ID, the type of action (corrective or preventative), its status (this will also show if any 'New' actions are overdue) and the area of service it applies to.

To view a record in detail, select it. This will now populate all of the information (where entered):

To start a review of this action, click Go to review. You can always return to this window by clicking Record details on the bottom or the tab of the same name.

When you click go to review you will see the review window:

Review screen -

It is here you will record all relevant information for the review.

The **date started** is auto populated once a review has been updated

Reviewer is where you record your name or initials

Incident themes are 6 drop downs to select themes from, you do not have to use all of them

Review notes is for recording any information relevant to the review

RCA is for the RCA

Action plan details is where you provide details of the action plan

If you are scoring the action, this is recorded in the **score** box

Final outcome should only be used when you are ready to finalise an action as complete, rejected or NA

A complete review may look like this:

Concessions -

If you need to record a concession against the action click the 'record concession' button at the bottom or 'concession details' tab below the selection window.

What is a concession?

A concession is a bit like a time extension for a non-conformance where the resolution is being worked on but will not necessarily be ready in the time frame for review. An example of this would be a document which is past its review, but its review is dependent on updated national guidance that is shortly launching. In this instance, you would raise a concession against the review date (essentially extending it) until the new guidance is launched. In short, it's like saying 'we acknowledge there's a problem & need a bit longer to resolve it".

This will take you to the concession screen.

Concession number is for the concession number to be recorded.

Concession length (days) is where you record the concessions length. When the action is saved the review start & expiry will auto-populate.

If a concession is already in place or ending you can record the outcome in the **concession outcome** textbox.

Once you've completed this click **return to review**

Update or complete action -

Once you have entered information you save it by clicking 'update action'. The action now have its status changed to 'under review' and will continue to show in the list until it's completed.

To finalise an action, click the drop down under 'final outcome' and select what the outcome is. When you update action now it will be recorded as 'complete'.

Create report -

If a senior colleague needs to authorise an action plan a report can be created by clicking 'create report' on the review window. This will create a new workbook with a summary of the action and space for feedback on the action plan.

Example Report:

CAPA Report			
Incident number:	18012445-535	Date raised:	18/01/2024
Reviewer:	Quality grp	Action type:	Corrective

Description
Patient attended R2 for issue of aids. She reported that she had had a sudden deterioration in hearing around 3 weeks before she was seen for R1. This may not be consistent with what she said at R1 as the notes say otherwise, but her hearing had dropped considerably and there is no mention of

Notes
clinician performed within her scope of practice - made onward urgent appt for further testing and hearing aid management. No action made on the day in regards to abnormal TM in right ear

RCA
clinician did not follow standards in asking for second opinion for ototoscopy:

Themes
[Training][Clinical Noting]

Action plan
emailed clinician regarding asking second opinion for otoscopy

SLT response

CAPA score:	4	Response date:	

General -

The review screen has lots of inbuilt prompts, so if you forget to enter something important it will likely show a message box to remind you before continuing.

4.   Manual review

Data from submissions goes directly into the 'CAPA DB' tab. The columns breakdown into several key groups:

ID &status, Record & record details, incident details, Review details, Themes, and concession details.

ID & status:

Whenever a new record is created it receives a unique ID, this can be found in column A.

Column B contains its current status, this is either 'New', 'Under review', 'Complete' or 'Closed', its really important you remember to change this status when needed (this happens automatically in the review screen).

Definition of terms

New – A new action which has not been reviewed yet

Under review – An action currently under review

Complete – An Action which has been completed i.e. RCA carried out & action plan put in place

Closed – An action closed for any other reason i.e. it may not fit the CAPA remit.

Record & Record details:

Record	Record Details								
Record Type	Raised by	Date submitted	Pt affected ?	K number	Area of service	Category	Related to document?	Relevant Document	Description
Corrective	Bob	22/08/2023	Yes	K1234	All	Other (Please detail)	I can't remember the document title		Testing	No
Corrective	Bob	20/08/2023	No		Unsure	Delay / failure to treatment or procedure	YES	Reassessment Pathway 6.6.1	information godes here	No

This section contains the key information about the submission. All of this information is populated from the CAPA submission.

Column C – contains the type of action – Corrective or Preventative

Column D – Shows who submitted it (unless they were anonymous)

Column E – shows the date of submission

Column F – shows whether the incident affected a patient

Column G – shows the affected patients ID number (if relevant)

Column H – shows the area of service the action applies to

Column I – shows the category of CAPA

Column J – details if the incident relates to a document/documented process

Column K – is the title of the document (where relevant)

Column L – it's a description of what happened.

Incident details:

If the user who raised the action also raised an incident*, this is where they would provide its details.

*This refers to you Trusts own incident management systems e.g. DATIX.

Column M – shows if an incident was raised (this is a drop down)

Column N – shows the incident number.

If, following an investigation, an action has to be transferred to the Trusts incident management system the details should be recorded here.

Review details:

This section covers information detailing the review of the submitted action, its here you will record the RCA & outcome.

Column O – Contains the date the review is due to start, this is auto generated when its submitted

Column Q – This is where you record the Date it was started in DD/MM/YYYY format

Column R – The name or initials of the reviewer

Column S – Any notes relevant to the review

Column T – The RCA for the action

Column U – The action plan to resolve the action

Column V – The outcome of the review. This is a drop down list with Accepted, Rejected or NA

Column W – is the Actions score as per the CAPA scoring index

Column X – is the date the review was completed in DD/MM/YYYY format.

Please remember that once a review is completed you need to change the status in column B.

Themes:

This section provides a more detailed analysis of the Action's themes beyond the one selected by the submitter.

Column Y provides a combination of all selected themes to allow easier filtering, column Z-AE are all drop downs listing theme options

	Y	Z	AA	AB	AC	AD	AE	
				Themes				
~w ~ted	Theme Summary		Please select Theme					Con
								No
								No

Concession details:

During the review process there may be need to raise a concession against an action, particularly if the review is taking some time. All the relevant details are recorded here.

AF	AG	AH	AI	AJ	AK	
		Concession Details				
Concession?	Concession Number	Concession Length (days)	Concession Review Starts	Concession Expires	Concession Outcome	
No		TBD				
No		TBD				

Column AF – is a drop down to select if there is a concession

Column AG – is where the concessions number is recorded

Column AH – is the concessions length in days

Column AI – Auto populates when the concessions review should start

Column AJ – Auto populates when the concessions expires

Column AK – is where you can record the concessions outcome.

This covers all sections for manual entry of information.

A note on timeframes:

The CAPA tool contains formula and formatting aligned with the following timeframes

- Corrective actions show as overdue if a review is not started within 28 days of being raised
- Preventative actions show as overdue if a review is not started within 84 days of being raised

4.1. Colour Key

The CAPADB tab has some conditional formatting to help highlight certain things:

Colour	Meaning
	New corrective action
	Action under review
	Review completed
	Review closed*
	Review start overdue
	New preventative action

*there may be instances where a review cannot be completed due to unforeseen consequences and needs to be closed.

5. Other sheets in the database

KPI's

The KPI's tab provides a comprehensive breakdown of Corrective and Preventative actions by category and theme across areas of the service as well as showing current performance measures such as how long it takes for reviews to be started and how long it takes them to be completed.

Reports

This tab can be used to generate a report of key CAPA information across a set time frame. Enter the start and End date into the light blue cells then click 'create report' this will generate a new spread sheet with the information.

Please enter Date range DD/MM/YYYY				All information presented is for actions raised within the selected time frame			change date in light blue cells before creating report
From:	01/04/2023	To:	31/03/2024				

Total submissions:	19
Corrective:	19
Preventative:	0

Create report

Status	Corrective	Prventative
New	1	0
Under Review	0	0
Complete/Closed	18	0

News overdue for review			
Corr.	1	Prev.	0

Area break-down by action type

Action	Clinical	Admin							
Corrective	0	0	0	0	0	0	0	0	0
Preventative	0	0	0	0	0	0	0	0	0

Corrective action Breakdown

Area & Category

Category	Totals	Clinical	Admin						
Access, Admission, Dis	0	0	0	0	0	0	0	0	0

Lists

This tab should mostly be left alone. However, Themes can be updated here. The themes are in column G and should only be entered in the light blue cells. Anything outside that will not be detected

Docs

This is where you record the titles of documentation used in the service. Document titles should be entered in the light blue cells. This populates the documents list used when submitting a CAPA.

Math

Best to leave this one alone.

General note:

This database has been left 'open' for you to adapt as you see fit, however, certain processes will cease to work if you move/delete parts of it, it will likely stop other parts functioning. The user screens in particular are set to populate set rows/columns and do not automatically shift to any changes.

The CAPA database is set to auto save itself on closure.