SOP04
Clinical Audit and Quality Improvement Standard Operating Procedure

1.0 Procedure Statement (Purpose / Objectives of the Procedure)

The Royal Wolverhampton NHS Trust is committed to developing a robust clinical audit programme to ensure the quality of service is of the highest standard and that improvements are continuously implemented.

Clinical audit is a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality, and taking action to bring practice in line with these standards so as to improve the quality of care and health outcomes (New Principles of Best Practice in Clinical Audit (HQIP, January 2011).

Whilst Clinical Audit is fundamentally a quality improvement process, it also plays an important role in providing evidence of assurance about the quality of services.

The primary objectives of clinical audit are to:

- Measure practice using agreed standards;
- Provide quality assurance to stakeholders (patients, staff and public);
- Identify areas which require improvement;
- Implement change where necessary;
- Monitor improvements.

This SOP sets out the Trust's expectations in relation to conduct and participation in clinical audit. The SOP outlines the process that must be followed when developing and designing clinical audit projects and the support that is available from the Assurance Department. The SOP applies to anyone engaged in the clinical audit process under the auspices of the Trust, including students and patients as well as staff.

2.0 Accountabilities

2.1 Trust Board

The Trust Board has a role in driving quality assurance, compliance, internal audit and "closing the loop" in accordance with *Healthcare Quality Improvement Partnership (HQIP) document: Clinical audit: a guide for NHS Boards and partners (2015)* available at www.hqip.org.uk

2.2 Chief Executive

The Chief Executive has overall responsibility for the strategic direction and operational management of the Trust and takes overall responsibility for this SOP.

2.3 Clinical Audit and Effectiveness Group (CAG)

The CAG provides assurance to the Trust Board through Quality Standards Advisory Group (QSAG) (or equivalent meeting) and is responsible for:

- Ensuring appropriate arrangements are in place to monitor the clinical audit activity within the Trust;

- Developing a Clinical Audit and Effectiveness Strategy which includes the participation in both national and local audits as well as establishing a system for the recording of audit activity;
- Evaluating the implementation of change through re-audits;
- Ensuring appropriate arrangements are in place for monitoring the Implementation of prioritised clinical effectiveness and audit programmes. The strategy must be reviewed every twelve months and include an Audit Plan for the twelve months period.

2.4 Chief Medical Officer

The Chief Medical Officer is the Executive Sponsor of the Trust's Clinical Audit Programme. The Chief Medical Officer reports and provides assurance to the Trust Board regarding compliance and completion of the clinical audit activity in the Trust.

2.5 Trust Clinical Audit Lead

The Clinical Audit Lead is the chair of the CAG and is responsible for the delivery of the clinical audit programme in the Trust. The Clinical Audit Lead is responsible for creating the strategy, for embedding clinical audit within the organisation and is actively involved in the dissemination of clinical audit information. The Clinical Audit Lead is responsible for the clinical audit budget. The Clinical Audit Lead provides a regular report to the QSAG regarding clinical audit activity within the Trust.

2.6 Divisional Management Team

The Divisional Management Teams will approve the annual clinical audit programme for each Division. They will oversee progress against the agreed plan for each Directorate. They will have overall responsibility for approving audits to be abandoned and ensuring a risk based approach to decision making.

2.7 Healthcare Governance Managers

The Healthcare Governance Managers are the deputy chairs of the CAG. They have overall responsibility for the operational activities of the Trust audit programme. The Healthcare Governance Managers approve the requests to abandon or remove audits (as approved by Divisional Management Team).

2.8 Governance Support Team Leader

The Governance Support Team Leader is responsible for establishing arrangements for the monitoring and reporting of clinical audit activity across the Trust. The Governance Support Team Leader reports progress against plan to Divisions bi-monthly. The Governance Support Team Leader has administrative access to Clinical Audit Database (CAD). They will add new Audit Conveners and remove audits as requested.

2.9 Directorate Management Team

Directorate Management Teams are responsible for agreeing the Directorate Annual Audit Plan and tracking progress against it. Audits identified to be abandoned must be agreed by the Directorate Management Team before escalation to Divisional Management Team. Clinical Managers must be aware of clinical audit activity within the Directorate, particularly if the anticipated outcome of a clinical audit project raises resource implications.

2.10 Clinical Audit Convener

Each Directorate has an identified Clinical Audit Convener who has the responsibility for the following.

- Agree the Directorate Clinical Audit Plan by the end of Quarter 4 for the next financial year.
- Co-ordinate clinical audit activity across the Directorate, including Medical, Nursing and AHP projects.
- Identify any training needs within the Directorate for the conduct of audit projects.
- Identify appropriate Audit Leads against required audit projects.
- To ensure the findings from National Audits are circulated as required including presenting at CAG or COG as necessary.
- All audits must be scored and prioritised accordingly.
- Approve audit projects in a timely manner, when they are uploaded onto the CAD.
- Agree the appropriate dissemination of the audit project findings and sharing lessons learnt.
- Ensure, in conjunction with the Audit Leads, the completion of audits in their Directorate and for taking recommendations to Directorate meetings for developing action plans.
- Ensure there are systems in place for the implementation of audit recommendations and closing the audit loop.
- Highlight demonstrable improvements to patient care.
- Ensure audit projects are recorded on the CAD once the audit plan has been agreed at the start of the Financial Year. Any additional audits will need to be approved and registered on CAD before the audit commences.
- Work with the Audit Leads to agree outcomes and capture this on the CAD.
- To ensure that the CAD is kept up to date as a “live” record detailing progress with audit activity within the Directorate.
- Represent the Directorate at the CAG meeting. Attendance by Audit Conveners at the CAG meeting must be at least 70%. If an individual is unable to attend a meeting then they must arrange to send an appropriate representation.
- Meet with their allocated Governance Officer on at least a bi-monthly basis to discuss and monitor progress against the agreed audit plan.
- All audits must be mapped to the Trust’s strategic objects and the CQC domains.

2.11 Audit Lead

The Audit Lead (also known as the Audit Supervisor) for each audit project must be a Consultant or other Senior Registered Practitioner (any profession). Junior Doctors wishing to undertake specific audits must approach their supervising Clinician to act as lead. Audits Leads have the following responsibilities.

- Liaise with all stakeholders to agree the specific criteria and standards to be measured by the audit.
- Discuss and agree the aims and objectives of the audits with the Audit Convener prior to registration of the audit on CAD.
- Use the CAD to register their audit and regularly update on the progress of the audit.
- Oversee the data collection stage of the audit.
- Present audit findings at relevant Directorate forums and ensure all actions are monitored through to completion.
- Ensure that their nominated audits are completed in a timely manner (as agreed in the Directorate’s Annual Audit Plan) and that their audits are managed through the CAD by liaising with the Audit Convener and Governance Officer.

- Once an audit has been presented at an appropriate forum the Audit Lead must ensure qualitative minutes of the discussion, including findings and agreed actions are uploaded to CAD. Either a report or the report tab needs to be completed once the audit has been completed.

2.12 Governance Officer

- Work with the Audit Convener to generate a realistic and robust audit plan.
- Facilitate clinical audit projects within the Directorate and support Audit Leads with methodology, audit tools and analytical tools.
- Promote the need to ensure the audit cycle is completed including the production of a robust report and action plan.
- Ensure any NICE Guidelines that are due to be audited are included on the audit plan.
- Promote and support the use of the CAD across the Trust.
- Provide training in the use of the CAD as required.
- Ensure any audit projects with findings that demonstrate moderate or significant non-compliance are re-audited in the subsequent financial year.
- Monitor and track the progress of audit projects via the CAD and report any areas of concern to the Audit Convener, Directorate Governance Meeting and to the Healthcare Governance Managers.
- Report any areas of non-compliance to the Governance Support Team Leaders and Healthcare Governance Managers.
- Identify lessons to be learned and share via the monthly Integrated Governance Report.

3.0 Procedure/Guidelines Detail / Actions

3.1 Definitions

Clinical audit involves collecting information about patient care and treatment, but more than that, it is about ensuring quality i.e. making sure we are doing what we must be doing. A standard is an explicit statement describing the quality of care to be achieved, which is definable and measurable. In order to effectively measure your performance, the standards developed need to be **SMART:**

Specific – clear and unambiguous
Measurable – easy to evaluate
Achievable – within your resources
Realistic – within service constraints
Timely – not out-of-date or inaccurate.

Quality Improvement Projects are rapid cycles of audit, where a deficiency has been identified and improvement must be implemented quickly. QIPs aim to improve the patient experience and can focus on more holistic issues or where there are no formal standards. A QIP should be a continuous process of learning, development and assessment.

3.2 The annual audit programme

Prior to the start of every financial year, Directorates will agree an appropriate planned programme of clinical audit activity. This programme must meet the Trust's corporate requirements, goals and objectives, for the assurance of patient care and service delivery. The audit programme must be owned locally by Directorates. Within the financial year

additional audits may be identified based on risk indicators or service needs and they will be added to the relevant annual plan. There is a limit of 10 local clinical audits or Quality Improvement Projects (QIP) per Directorate. This figure excludes mandatory audits (as described below). Once the 10 local audits or QIPs have been completed, Directorates can add further audits to their audit plan.

3.3 Selecting audit topics

3.3.1 Mandatory audits

These are audits that are compulsory for the Trust to demonstrate compliance:

- Participation in the National Clinical Audit Patient Outcome Programme (NCAPOP);
- Audits identified for inclusion in the Quality Accounts;
- NICE Guidance (as per Trust Policy);
- Trust wide mandated audits.

3.3.2 Local audits and quality Improvement projects (QIP)

Local audits are not necessarily national priorities, but are important to the Trust in delivering patient care. All local audit projects must contribute to the overall objectives of the audit programme and look to improve patient care / service delivery. Drivers for local audit may include incident trends, risks or complaints. All audits are prioritised and will be aligned to the Trust strategic objectives and mapped to the five CQC domains.

3.4 Involving patients and the public

The Trust must involve patients and, or carers in the clinical audit process either indirectly through the use of patient surveys and service evaluations or directly through participation of identified individuals on project steering groups or patient forums.

3.5 Multidisciplinary audit and partnership working

The Trust must make sure clinical audit is undertaken jointly across professions and across organisational boundaries. Partnership working with other local and regional organisations will be encouraged where improvements to the patient journey may be identified through shared clinical audit activity.

3.6 Involving medical students and junior doctors

All the audit projects taken up by Medical Students or Junior Doctors must have a designated Audit Lead and must be registered on the CAD. All Trainees are expected to undertake a Clinical Audit or Quality Improvement Project. This project must be of benefit to the organisation and the trainee must complete the audit cycle, ensuring their audit is presented, any recommendations are discussed, appropriate actions are agreed by the Directorate and a formal report submitted.

3.7 Audit plan approval process

All Directorate audit plans must be agreed at an appropriate local forum by the end of February in Quarter Four. Every audit must state which Quarter the audit is planned to be completed. This is tracked and monitored throughout the year by the Governance and Divisional Teams. The Directorate Audit plans will then be signed off by the appropriate

Divisional Governance meeting prior to the end of the financial year.

3.8 Registering and approving audits

All clinical audits conducted within the Trust must be registered via the electronic CAD available via the Trust intranet webpage. All audit projects within a Directorate must be approved by the Audit Convener and monitored by the Directorate.

Clinical audits registered on the CAD outside of the originally agreed plan will be monitored on a continual basis by the Governance Officers. An audit which has been initially registered but not had all mandatory fields completed in order for approval to be issued by the Audit Convener will be declined by the Governance Officer after 1 month. The lead who registered the audit will be contacted and advised of the need to complete the outstanding fields on the CAD or the audit will be declined as will be presumed not a priority for the Directorate.

Once registered on the CAD the audit project must be completed within the identified quarter of that financial year (including completion of a clinical audit report), as detailed on the audit plan. New clinical audits must not be registered in the last quarter of the financial year (apart from in exceptional circumstances).

3.9 Process for ensuring appropriate standards of performance are audited

All audit projects must have a project aim, identified Audit Lead and expected timescale for completion (quarter due). There are six key stages within an audit project which are referred to as the audit cycle (outlined in Appendix 1) and each project must reflect “Criteria for Good Audit” (detailed in Appendix 2). The Clinical Audit Process is outlined in Appendix 4.

Wherever possible, prospective clinical audit must be the norm as it allows for accurate real time accrual of data that reflects current rather than historical practice. Data collection must therefore be 100% accurate both in volume and detail. A good audit tool ensures data quality is not dependent on the interpretation of the audit criteria. The data must be the same regardless who is collecting the data. Retrospective clinical audit can however act as a historical benchmark, but is of most use if a critical incident arises be this via a complaint, litigation, adverse event or serious adverse outcome and a review of practice is required urgently.

For locally led audit projects, patient notes can be accessed via the Clinical Web Portal, assuming the appropriate Information Governance processes have been followed in order to access patient notes. Caldicott guardian principles must also have been taken into account and adhered to.

The Trust takes the view that, wherever possible, registration of audit projects must include the adoption of credible evidence based standards but notes that standards do not always exist in relation to local projects in particular. In this case the expectation will be that local standards or best practice guidelines will be agreed.

3.10 Reporting and dissemination of results

Each completed audit must have a final report which includes the sections outlined in Appendix 3. When the final report has been produced, it must be attached to the CAD.

Alternatively, findings and results must be included in the 'Report' tab on the CAD.

The results of audit must be disseminated appropriately at specialty and Directorate meetings where the findings must be discussed and action plans developed. Where issues of moderate or significant non-compliance are identified it may be appropriate to consider adding any risks identified to the Directorate's risk register, including actions required for achieving compliance.

Any audits that require Directorate action must be disseminated to, at least, the appropriate Clinical Director, Directorate Manager, Matron & Audit Convener (by their designated Governance Officer). It must also be presented at the appropriate local forum (Governance or Audit meeting).

3.11 Developing effective action plans

Local clinical audit reports will be reviewed and where any non-compliance or deficiencies in practice are identified, a SMART action plan must be developed and approved and monitored at an appropriate local forum (normally Governance or Audit Meeting).

This SMART action plan must be recorded on CAD. Actions must have clearly defined timescales and an identified lead. Where the audit identifies actions involving staff outside of the Directorate, the Audit Lead must communicate, discuss and agree with the appropriate persons in good time to allow for the action to be completed within the defined timescales. If any barriers to change or organisational / resource constraints are encountered, the appropriate route of escalation must be identified.

Not all clinical audits will require an action plan, for example where audit shows full compliance against standards or guidance. For such audits there must be an explicit statement saying "no further action required" in the audit summary report and rationale given for re-audit not being required.

Trust wide audit reports will be presented at the Clinical Audit Group (CAG) and final approval of the report lies with the Trust audit lead. The group will review the results and actions to ensure they are accurate and appropriate. Reports will then be presented at a local level by the Governance Officer. The specialist/parent group or Directorate is responsible for ensuring that all actions identified from Trust wide audits are completed and updated on the CAD.

3.12 Improvement

Improvements from an audit can be seen through a number of different outcomes, such as: a reduction in incidents, a reduction in risks, improved clinical outcomes, increased efficacy and efficiency, cost savings, improved patient experience, and re-audit showing better clinical results or compliance against agreed standards.

When proposing an audit, the CAD requires the Audit Lead to register expected improvements as a result of the audit (project aims and outcomes). Post-audit it will be established whether the improvements were achieved and any further actions required. This action plan must be recorded on the audit database. Actions must be tracked to ensure they are completed against the agreed timescales.

3.13 Re-audit

Re-audit is important to determine whether agreed actions have been implemented and

whether these demonstrate improvements. Re-audit must be part of the annual clinical audit programme and all initial audits with corresponding action plans must be considered for re-audit where moderate or significant non-compliance is indicated. To demonstrate improvement, a comparison of the results between a first audit and subsequent re-audits must be completed and must be included within the conclusions.

There must be a commitment to re-audit to ensure that an evaluation is undertaken of any implemented changes in practice to determine whether they have yielded improvements to patient care or service delivery.

3.14 Process for abandoning audits

Audits identified by the Audit Lead as needing to be abandoned must be discussed and agreed with the Directorate's Audit Convener and then presented at an appropriate forum to the Directorate Management Team for agreement, ensuring a risk-based approach to decision making. The CAD will be updated to reflect the status and rationale and the Governance Support Team Leader will include in the Divisional monthly audit progress report. The Healthcare Governance Managers will then escalate requests to abandon to the Divisional Management Team who have overall responsibility for approving audits to be abandoned.

3.15 Information Governance; Legal Basis for Processing

All Clinical audit activity must take account of the Data Protection Law (GDPR and Data Protection Act 2018) and the Caldicott Principles (1997). This means, for example, that data must be:

- Adequate, relevant and not excessive;
- Accurate and up to date;
- Processed for limited purposes;
- Held securely;
- Not kept for longer than is necessary.

All data collected must be anonymised or unattributable to an individual patient unless there is a compelling reason not to do so. In that case patients must be informed (under section 60 of the Health and Social Care Act 2001 which makes provision for the collection of patient identifiable data for the purposes of clinical audit) and they must give consent (see 3.16 below). For more detail on the legal basis for processing and the consideration for GDPR see OP12 IG/GDPR policy, OP97 **Confidentiality Code of Conduct for Staff** and Health Records Policy OP07.

3.15 Duty of Confidentiality

Whilst there may be a legal basis to process data for audit proposes (see section 9.4 for detail) where patient data is used in an identifiable form consideration must also be given to whether there are any issues with duty of confidentiality. Where it is not practical to seek consent for a large cohort of patients and gaining consent is not practical, it may be appropriate to seek a 251 application from the confidentiality group. Valid 251 will allow you to set aside the duty of confidence and process data for the purpose the application is granted.

3.16 Consent

Before any data is processed considerations need to be given as to whether or not consent is needed. For more guidance on consent and the legal basis for processing see OP07.

Consent must be freely given; this means giving people genuine ongoing choice and control over how you use their data. Consent should be obvious and require a positive action to opt in. Consent requests must be prominent, unbundled from other terms and conditions, concise and easy to understand, and user-friendly.
Consent must specifically cover the audit name, the purposes of the processing and the types of processing activity. Explicit consent must be expressly confirmed in words, rather than by any other positive action.

3.17 National opt-out

The National opt-out policy enables patients to opt-out from the use of their data from anything other than their care and treatment; this includes use of their data in clinical audit projects. By 2021 all healthcare organisations are required to be compliant with the national data opt-out policy. Local clinical audit is part of the definition of individual (direct) care used within the National Data Guardian Review and therefore is not included in the scope for the national data opt-out. All National audits the Trust participates in must be assessed for inclusion in the National opt-out policy. Exemptions from the opt-out process include audits that:

- Take consent;
- Have a local opt out process already in place;
- Use anonymised data only;
- Are being provided under S259 (Health and Social Care Act).

The Trust has established a system to send data to the Messaging Exchange for Social Care and Health (MESH) so patients who have confirmed they wish to Opt Out will not be included in any audits. Audit leads are responsible for ensuring compliance with the National opt-out for clinical audits. Appendix 6 *The National Opt-out Clinical Audit Flowchart* details the process that needs to be followed.

See OP13 Appendix C – National Data Opt Out Policy Statement for further information.

3.18 Ethics

By definition, clinical audit projects will not require formal approval from a Research Ethics Committee. However one of the principles underpinning clinical audit is that the process must do no harm. Clinical audit must always be conducted within an ethical framework.

The ethical framework will consider the following four principles:

- There is benefit to existing or future patients or others that outweighs potential burdens or risks;
- Each patient's right to self-determination is respected;
- Each patient's privacy and confidentiality are preserved;
- The activity is fairly distributed across patient groups.

4.0 Equipment Required

4.1 CAD

The CAD is a web based application, accessed via the Intranet home page. It is a central repository for all clinical audit activity undertaken across the Trust. It is accessible to all clinical staff and the Assurance Department via Clinical Web Portal log-in details (for monitoring and quality assurance purposes). All clinical audits must be registered on the CAD. The CAD reporting suite enables us to search, monitor and report on all audits across the Trust. The CAD user guidance can be found in Appendix 5.

5.0 Training

Specific aspects of clinical audit require specialist skills to enable successful clinical audit, for example using the correct clinical audit methodology. The Trust will ensure all clinicians and other relevant staff conducting and/or managing clinical audits are given appropriate time, knowledge and skills to facilitate the successful completion of the audit cycle.

The Trust will make available suitable training, awareness or support programmes to all clinicians regarding the Trust's systems and arrangements for participating in clinical audit as required. Governance Officers are available to provide training and assistance when needed.

6.0 Financial Risk Assessment

1	Does the implementation of this document require any additional Capital resources	No
2	Does the implementation of this document require additional revenue resources	No
3	Does the implementation of this document require additional manpower	No
4	Does the implementation of this document release any manpower costs through a change in practice	No
5	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff.	No
	Other comments	

7.0 Equality Impact Assessment

An initial equality analysis has been carried out and it indicates that there is no likely adverse impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010.

8.0 Maintenance

This SOP will be reviewed every 4 years. Responsibility lies with the Clinical Audit and Effectiveness Group (CAG) chaired by the Trust Clinical Audit Lead for review and ratification of the SOP.

9.0 Communication and Training

Approved Trust SOPs will be made available to all staff via the Trust intranet page. This SOP will be updated and then communicated through the work of the CAG. The reviewed SOP will also be sent electronically to all Directorate Audit Conveners.

10.0 Audit Process

No formal auditing of this SOP is required.

11.0 References - Legal, professional or national guidelines

- British Royal Infirmary Inquiry (2002). Learning from Bristol. The report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. London: The Stationery Office.
- Clinical Governance Support Team (2005). A Practical Clinical Audit Handbook. London: Clinical Governance Support team.
- Darzi, Professor the Lord (2008). High Quality Care for All: NHS Next Stage Review Final Report. London: Department of health.
- DH (1997). The New NHS – Modern, Dependable. London: Department of Health.
- DH (1998). A First Class Service. London: Department of Health.
- DH (1999). Clinical Governance – Quality in the NHS. London: Department of Health.
- DH (2006). Good Doctors, Safer Patients: Proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients. A report by the Chief Medical Officer. London: Department of health.
- Healthcare Quality Improvement Partnership (22015). A guide for NHS Boards and partners. London: HQIP. **9.** Healthcare Quality Improvement Partnership (HQIP) (2009b). Criteria and Indications for best practice in clinical audit. London: HQIP.
- Healthcare Quality Improvement Partnership (HQIP) (2009c). Ethics and Clinical Audit and
- Quality Improvement - a guide for NHS Organisations. London: HQIP.
- National Institute for Health and Clinical Excellence (2002). Principles for Best Practice in Clinical Audit. Oxford: Radcliffe Medical Press.

11.0 Appendices

Part A - Document Control

Procedure/ Guidelines number and version Clinical Audit and Quality Improvement	**Title of Procedure/Guidelines** Clinical Audit and Quality Improvement Standard Operating Procedure Version 7		**Status:** Final	**Author:** Trust Clinical Audit Lead **For Trust-wide Procedures and Guidelines Director Sponsor:** Chief Medical Officer
Version / Amendment History	Version	Date	Author	Reason
	1.0	Sept 2006	Trust Clinical Audit Lead	Policy creation
	2.0	April 2008	Trust Clinical Audit Lead	Review and Amendments
	3.0	Nov 2011	Trust Clinical Audit Lead	Policy redo taking into consideration HQIPP standards for clinical audit
	3.1	Aug 2012	Trust Clinical Audit Lead	NHSLA requirement
	3.2	Sept 2013	Trust Clinical Audit Lead	NHSLA requirement
	4.0	February 2015	Trust Clinical Audit Lead	Review and Amendments
	5.0	March 2018	Trust Clinical Audit Lead	Transfer to SOP format, review and update policy
	6.0	March 2021	Trust Clinical Audit Lead and Governance Support Team Leader	Review and Amendments
	6.1	October 2024	Trust Clinical Audit Lead and Governance Support Team Leader	Extension applied
	6.2	July 2025	Trust Clinical Audit Lead and Governance Support Team Leader	Extension request

	7.0	July 2025	Trust Clinical Audit Lead and Governance Support Team Leader	Review and Amendments

Intended Recipients: All staff involved in Clinical Audit Activity within the Trust	
Consultation Group / Role Titles and Date: Healthcare Governance Managers, Governance Support Team Leader and Trust Clinical Audit Lead.	
Name and date of group where reviewed	Trust Policy Group September 2025
Name and date of final approval committee (if trust-wide document)/ Directorate or other locally approved committee (if local document)	Trust Policy Group - September 2025
Date of Procedure/Guidelines issue	September 2025
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	September 2029 - Every 4 years
Training and Dissemination: Policy will be made available to all staff through the Trust intranet. Policy to be distributed to all Audit Conveners and Governance Officers.	
To be read in conjunction with: Clinical Audit and Effectiveness Strategy	
Initial Equality Impact Assessment: Completed Yes **Full Equality Impact assessment (as required): Completed NA** If you require this document in an alternative format e.g., larger print please contact Policy Administrator for Trust- wide documents or your line manager or Divisional Management office for Localdocuments.	
Contact for Review	Trust Clinical Audit Lead
Monitoring arrangements	Clinical Audit and Effectiveness Group
Document summary/key issues covered. This SOP sets out the Trust's expectations in relation to conduct and participation in clinical audit. The SOP outlines the process that must be followed when developing clinical audit projects.	
Key words for intranet searching purposes	Clinical audit

Appendix 1: The Audit Cycle

Stage One: Selecting a topic
There can be many reasons for undertaking an audit project however the main reasons are perceived as being high risk, high cost, high volume, wide variation in practice or local concern. Topics for audit may originate from:

- NICE guidelines
- Confidential Enquiries
- National Audits / Royal Colleges
- Audits identified for inclusion in the Quality Accounts
- Trust wide audits
- Re-audits (of moderately or significantly non-compliant audits)
- Incidents captured by risk management process
- Complaints & Claims
- Risk assessments
- Case reviews
- Local guidelines and protocols

Stage Two: Set standards
Clinical audit measures current practice against guidelines or performance criteria. Consequently, explicit evidence-based standards should be identified for each project.

Stage Three: Data collection
Numerous methods are available for both quantitative and qualitative data collection to determine whether current practice complies with the agreed standards. In addition, where appropriate, projects should recognise the need for active patient, carer and public involvement, and the involvement of other organisations in the local Health Economy. Where an area does not interact directly with the public they should ensure the involvement of service users.

Audit is primarily a snapshot in time of current practice. The sample should be small enough to allow for rapid data acquisition, but large enough to be representative. It is recommended that small-scale pilot projects are undertaken initially to identify any potential problems with the data collection method before embarking on the main study.

Stage Four: Analysis and reporting
Data analysis and reports should be produced which focus on all the key areas of the audit including recommendations and changes to practice as appropriate. Reports must be presented within a suitable timeframe and to a suitable standard. The final report has to be logged on to the Trust's Clinical Audit Database.

Stage Five: Implementing Change / Making Improvements
The implementation of change is a key stage of effective audit and all affected parties must be informed of the results and understand the need for change and the changes recommended. A systematic approach should be adopted with each recommendation identifying the date by which it should be implemented and the person responsible for making it happen.

Stage Six: Re-audit

Once sufficient time has elapsed for changes to become implemented into practice, it is essential that a re-audit is undertaken to "close the loop" and demonstrate that improvements have been achieved, to patient care or service delivery. It cannot be merely assumed that changes will always result in positive outcomes.

Re-audit will need to address whether standards remain realistic and appropriate. Data should be collected by the same method as previously and compared accordingly.
The clinical audit process is a continuous quality improvement process and is often referred to as an "audit spiral" with opportunities for change becoming less as practice improves.

Ethical Responsibilities

Whilst audit projects do not routinely require ethical approval, project leads should be mindful of potential ethical concerns and seek advice as appropriate, in addition to paying appropriate recognition to the Caldicott recommendations, (recommendations available from, Trust Intranet homepage, GDPR, Caldicott Principles).

Appendix 2: Criteria for "Good Audit"

1. Should be part of a structured programme.
2. Topics chosen should in the main be high risk, high volume or high cost or reflect National requirements e.g. NICE guidelines, NSFs, National Clinical Audit Programme and Confidential Enquiries.
3. Service users should be part of the clinical audit process.
4. Should be multidisciplinary in nature.
5. Clinical audit should include assessment of process and outcome of care.
6. Standards should be derived from good quality guidelines.
7. The sample size chosen should be adequate to produce credible results.
8. Managers should be actively involved in audit and in particular in the development of action plans from audit enquiry.
9. Action plans should address the local barriers to change and identify those responsible for service improvement
10. Re-audit should be applied to ascertain whether improvements in care have been implemented as a result of clinical audit.
11. Systems, structures and specific mechanisms should be made available to monitor service improvements once the audit cycle has been completed.
12. Each audit should have a local lead.

Practical Clinical Audit Handbook, NHS, 2005

Appendix 3: Clinical Audit Report Writing Structure and Format

A good audit reports could contain the following headings and contents. The starred Headings are mandatory for all Clinical Audits completed within the Trust.

Title Page
This will include the title of the report, who has written it and the date it was written. Trust logo should be on the top right hand corner.

Contents Page
This lists the headings in the report together with the page numbers to which they refer.

Executive Summary
This should contain an overview of the message in the report, with a clear summary of the recommendations. This will be presented at Directorate Governance Meetings (or other appropriate forum) for discussion and approval of any actions as required.

Introduction/Background*
These can be two separate sections or combined. It must set the context of the report and define the scope and any limitations of the study.

Aims and Objectives
This must clearly identify what you want to achieve.

Standards
This section documents any standards which are being used to measure current practice against. It should include the relevant evidence base from which the standards are taken.

Methodology*
This section details how the study was undertaken. It must include how the information was collected, when project was undertaken, where it was taken from and how much e.g. if a survey was used – how was the survey carried out, how was the target population determined, how many were surveyed and how they were surveyed (by interview or questionnaire).

Results*
This is the main body of the report from which the author's ideas are developed. It must include the main findings in a logical and progressive manner, this can be interspersed with graphs to assist understanding. It must contain the requisite information to justify the conclusions and recommendations which follow. if re-audit is carried out, please provide comparable of previous results.

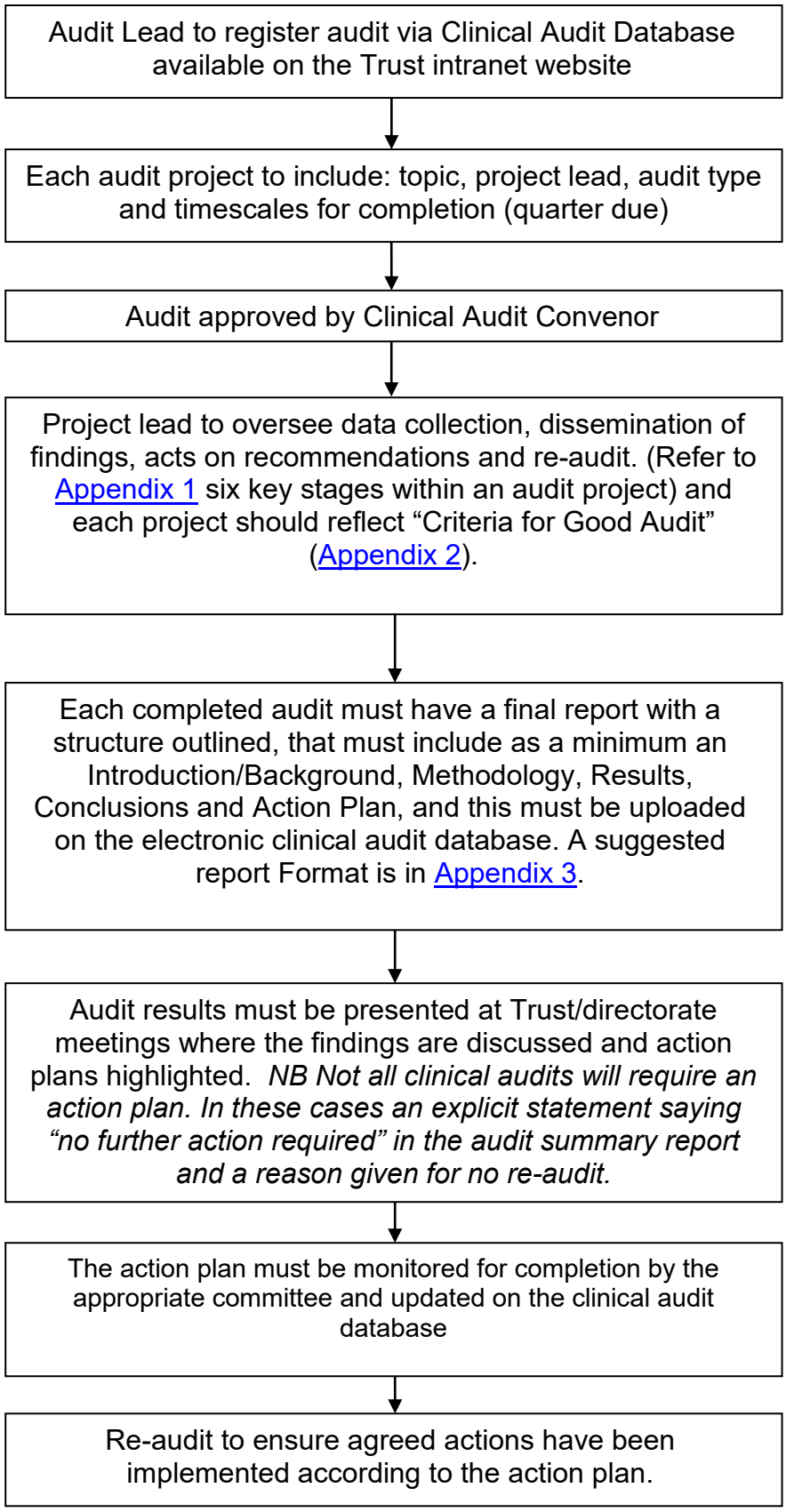
Conclusions*
These are derived from the results section and must also link back to the aims and objectives. No new information should be included. Bullet points are a recommended way for emphasising the key points. *For re-audits a comparison against the previous audit(s) results must be included.*

Recommendations
This section highlights the actions which need to be taken to follow on from the project. As with the conclusion section, recommendations must be derived from the main body of the report and should not include new information.

Action Plan*
All reports must include an action plan where recommendations have been made. It must include the action required, who has responsibility for doing it and the date it must be completed by, if necessary date and plan for re-audit.

References
All items referred to in a report must be appropriately referenced using the Harvard system.

Appendix 4: Clinical Audit And Quality Improvement Process Flowchart



Clinical Audit Database General User Guide

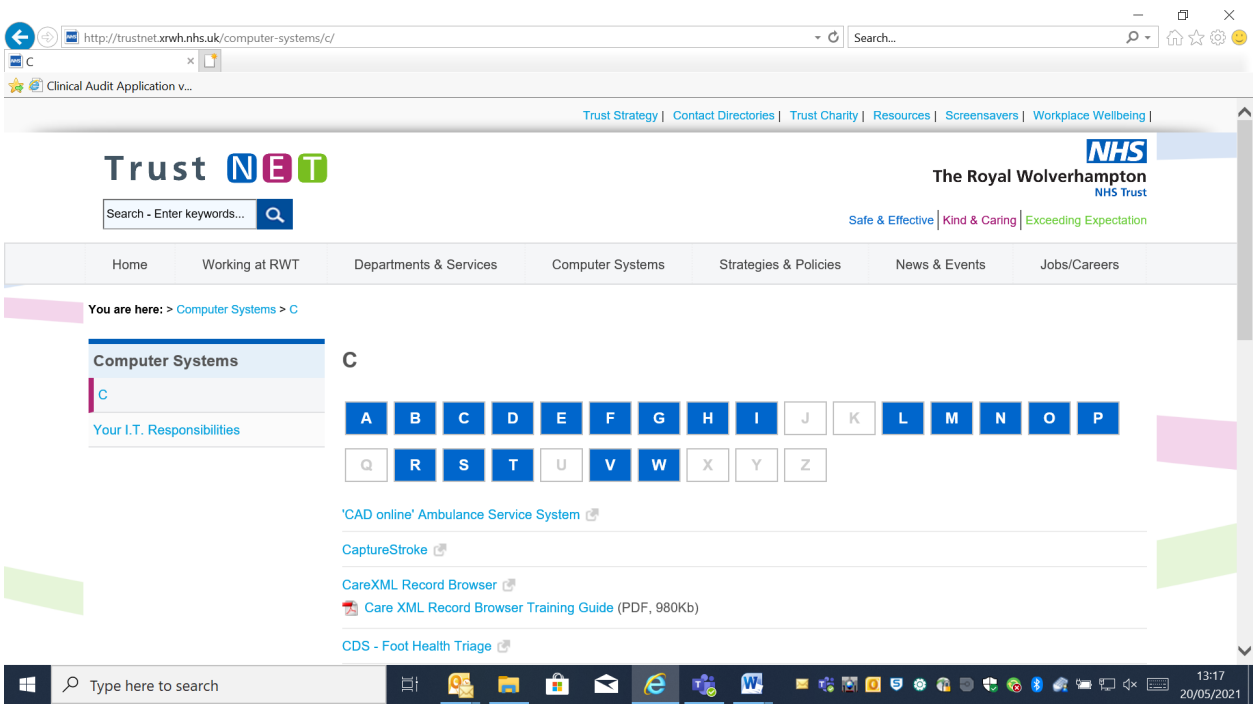
Contents

1. What is the Clinical Audit Database?

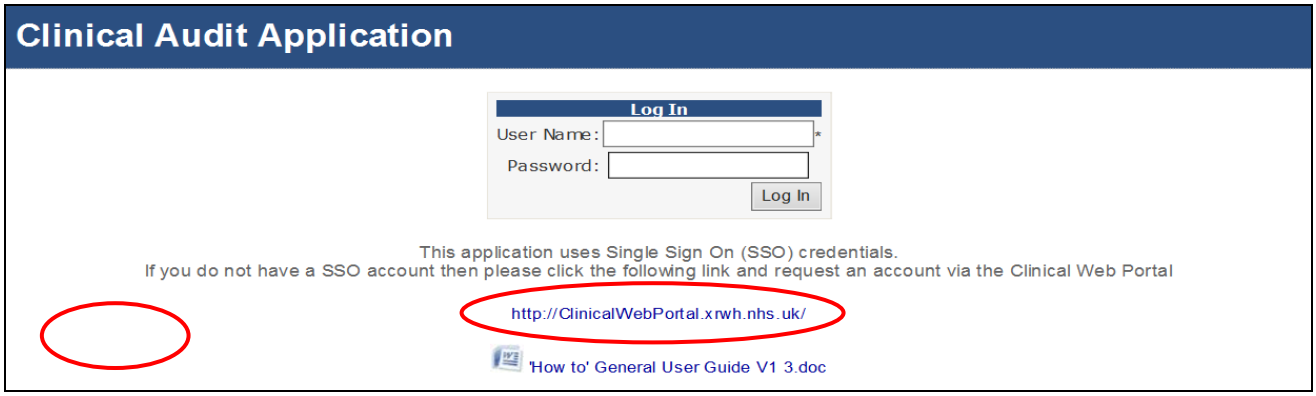
The Clinical Audit Database (CAD) is a web based application which allows users to register audits online, update on their progress, record compliance against audit standards and capture actions. It also provides tools to monitor and report on audit plan completion. This user guide demonstrates how to use all the functions of CAD.

2. Accessing CAD

The link to CAD can be located on the intranet home page, under **'Computer Systems**. Click on letter 'C' and scroll to the link entitled **'Clinical Audit'** and this will take you to the home screen of the CAD.



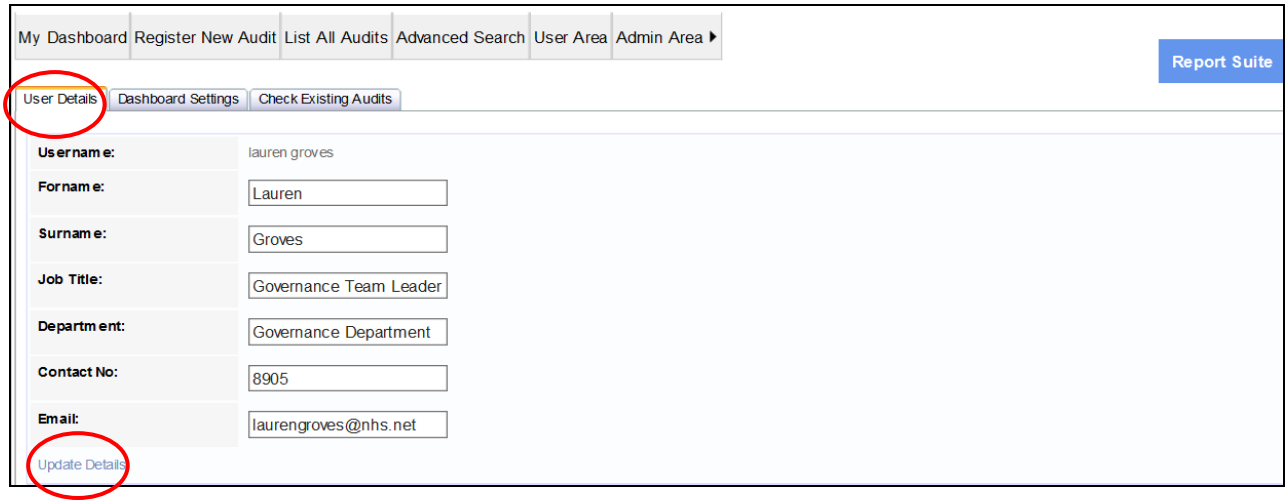
Log in to CAD using your **Clinical Web Portal (CWP) user name and password**. If you do not have a CWP user name and password, you can request them by clicking the available link.



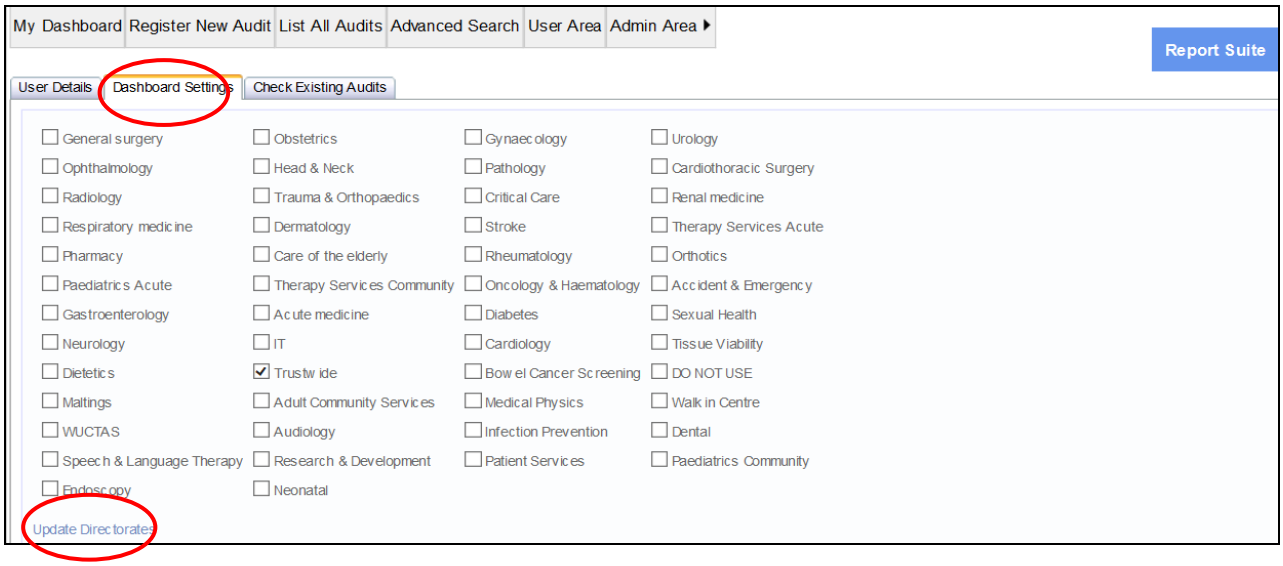
3. My dashboard

Once logged in, the first screen shows a list of all audits that relate to the Directorates listed in your '**User Area**' (plus any audits you are involved in either as the proposer or a member. You can select existing audits by clicking on the 'edit button'.

User details: On your first log in to CAD you will need to update your preferences. Click on the tab called **user area**. Complete the required fields on the 'User Details' tab. Once completed click 'Update Details' at the bottom of the page.

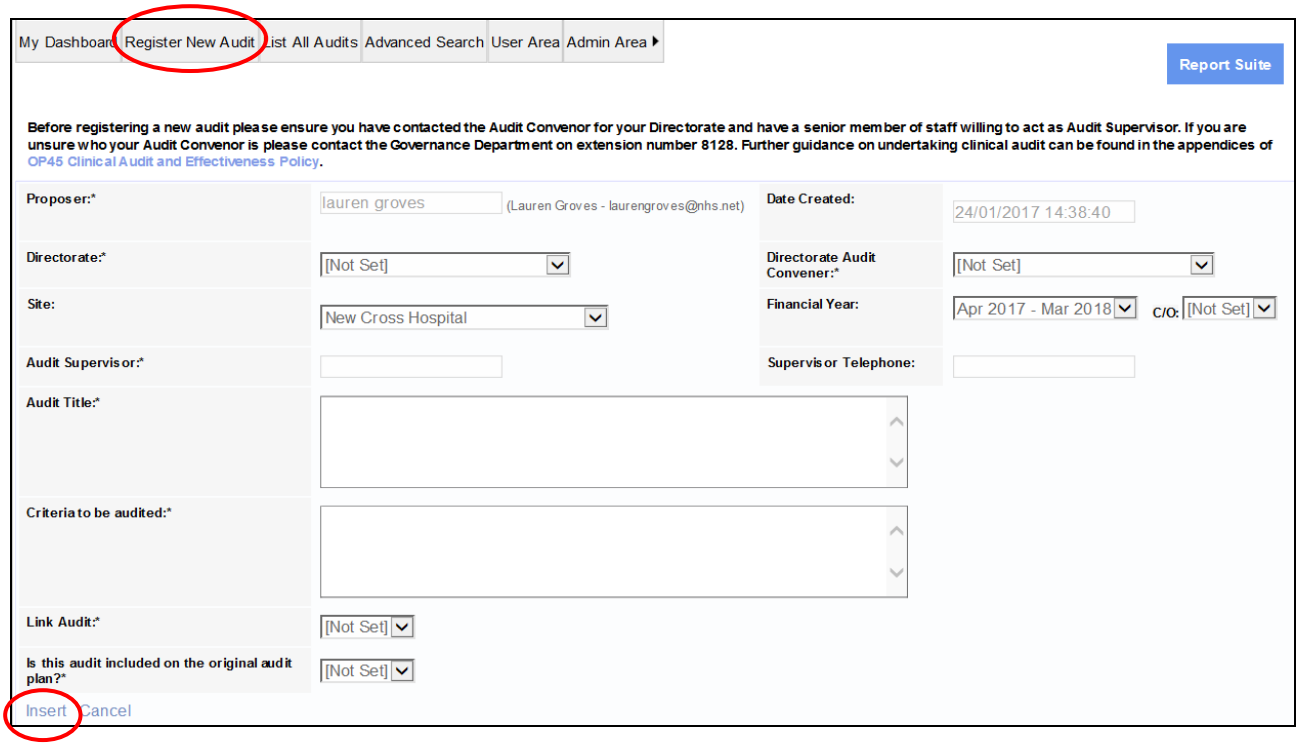


Dashboard settings: Next, select the required fields on the 'Dashboard Settings' tab. Once selected, click **'update directorates'**.

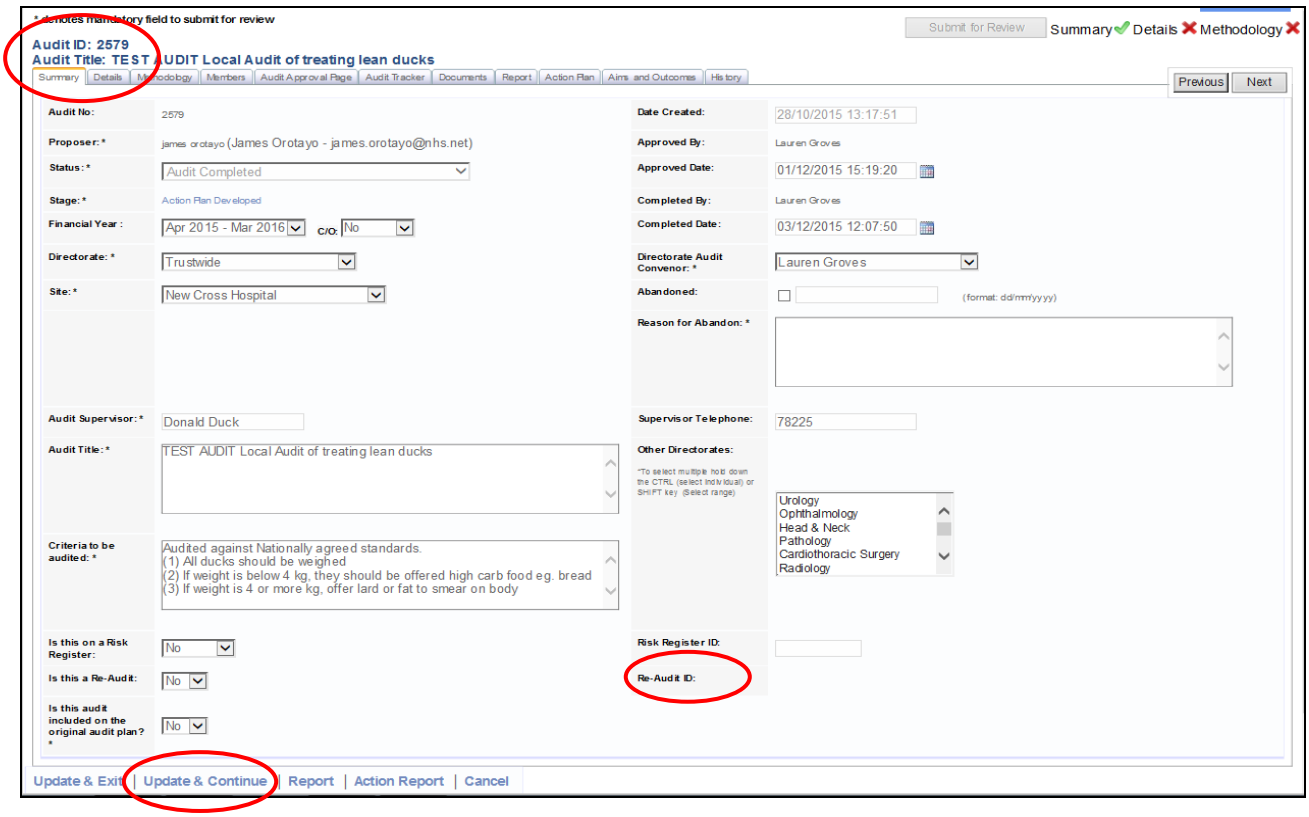


4. Registering a new audit

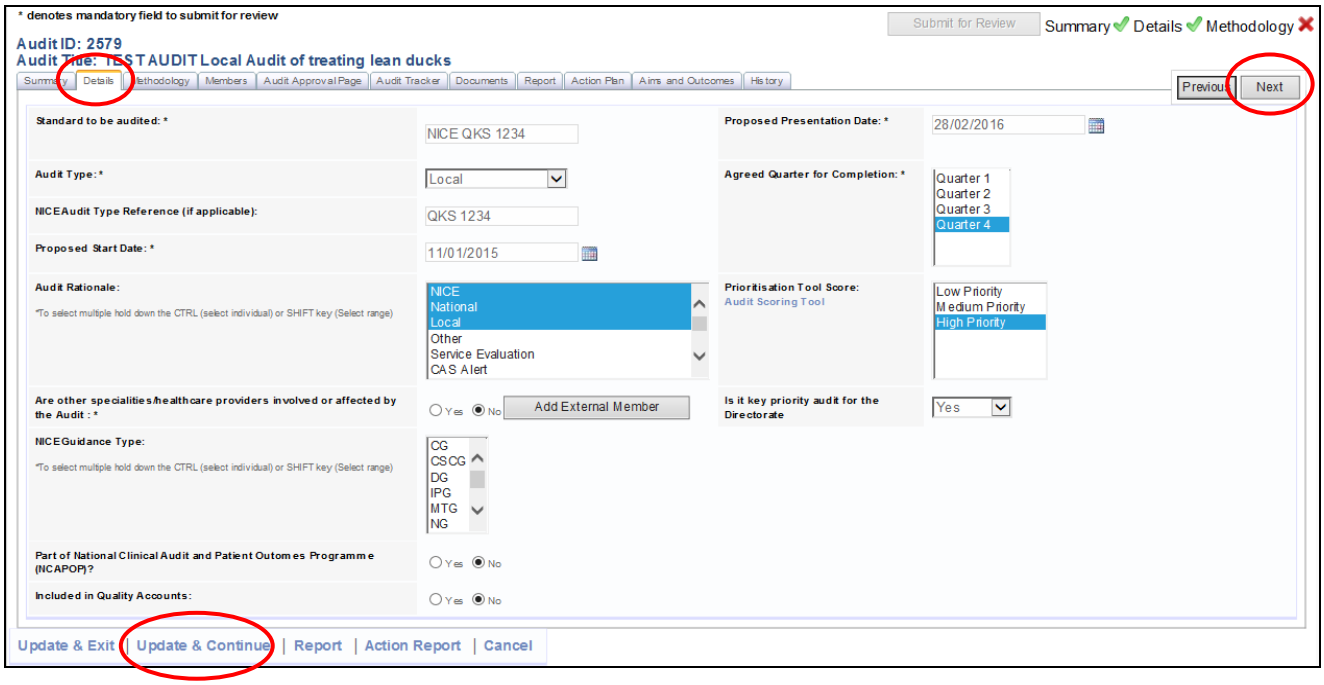
To register a new audit, click on the **'register new audit'** tab. When all required fields are completed, click **'Insert'.** This will create your audit project on CAD and take you to the next screen to complete registration.



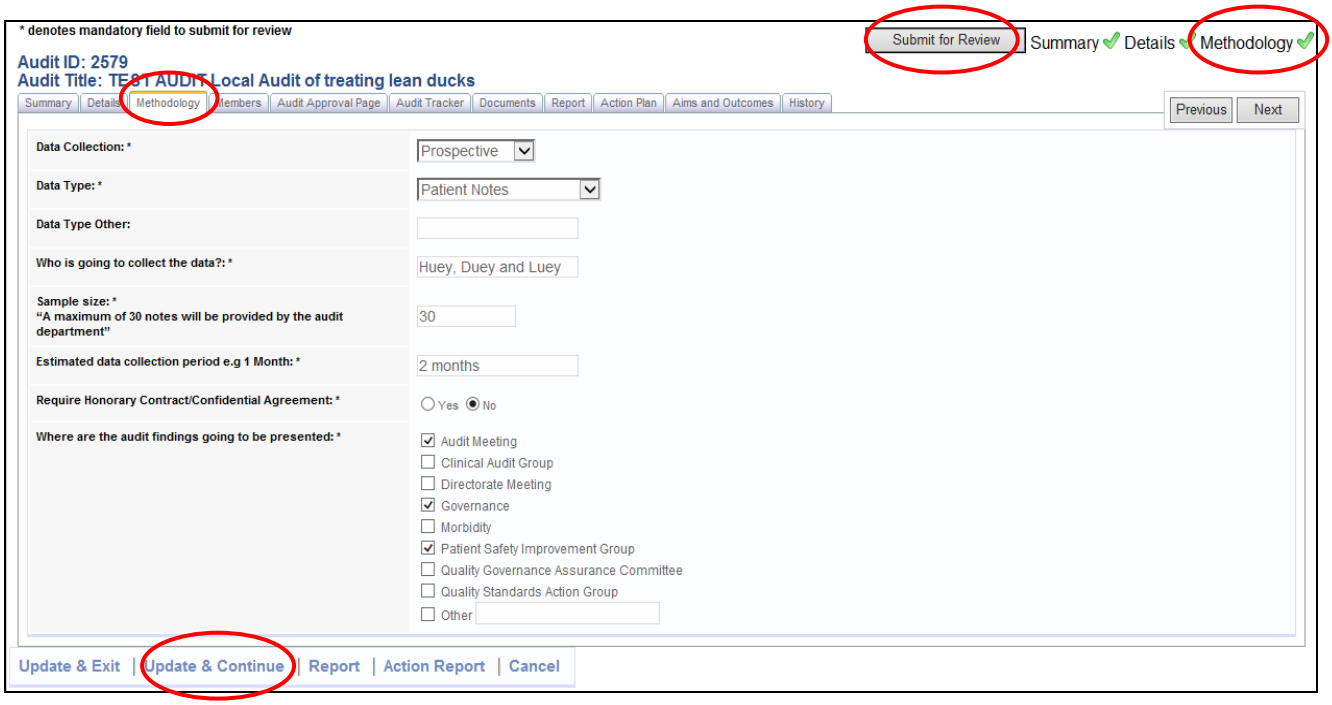
Summary tab: Once an audit has been created, you will be taken to the **'summary'** tab. The required fields must be populated. Once complete, you will see a green tick in the top right hand corner of the screen. This indicates all relevant fields have been completed on the summary tab. Always click **'update & continue'** before moving to the next tab. Note your Audit ID number. If applicable, enter the previous audits ID to link the two audits.



Details tab: Click the **'next'** button or on the **'details'** tab to move on to the next screen. Again, ensure all of the required fields are completed. This will give another green tick in the top right hand corner of the screen. You must click **'update & continue'** before moving to the next tab.



Methodology tab: Again, click the **'next'** button or on the **'methodology'** tab to move to the next screen. Ensure all of the required fields are completed. This will give another green tick in the top right hand corner of the screen. Click **'update & continue'.** All mandatory fields should now be completed. You must now click **'submit for review'** which will automatically send an email to the directorate's Audit Convenor to notify them that a new audit project has been registered, so that they may review and approve it.



The user will receive an email informing them whether their proposed audit has been approved or not. The user can follow the link within the email to go back to the audit database and log on to view the approved/declined audit. Alternatively, the audit will show on the user's dashboard the next time they log in to CAD.

Before your audit will be approved you will need to complete the first section of the **'aims & outcomes'** tab. Please see Section 10 below for details.

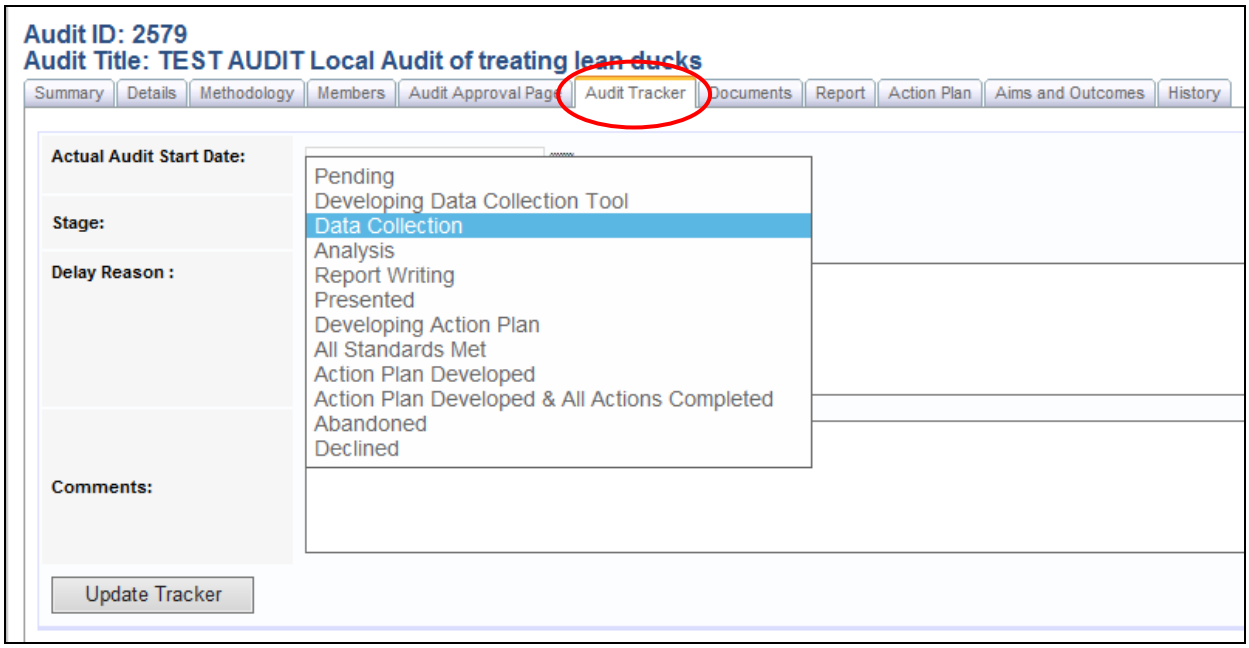
5. Audit approval

The approval status of the audit and any comments from the Audit Convenor (for example, if further information is required before approving the audit) is available via the **'audit approval page'** tab.

6. Audit tracker

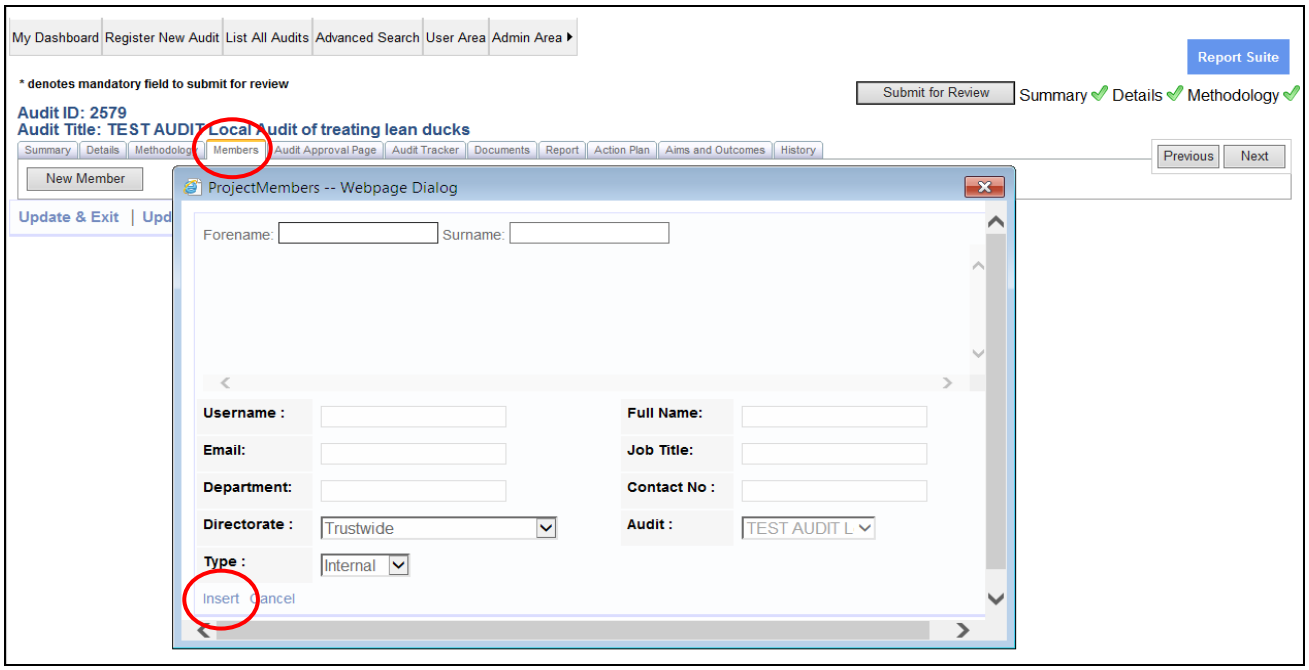
The **'Audit tracker'** tab allows you to update the audit stage (eg data collection or report writing). The Audit Convenor and Governance Officer can then monitor progress made

against an audit, including rationale for any delays. Users are able to go back to this page to update when necessary, using the drop down list.



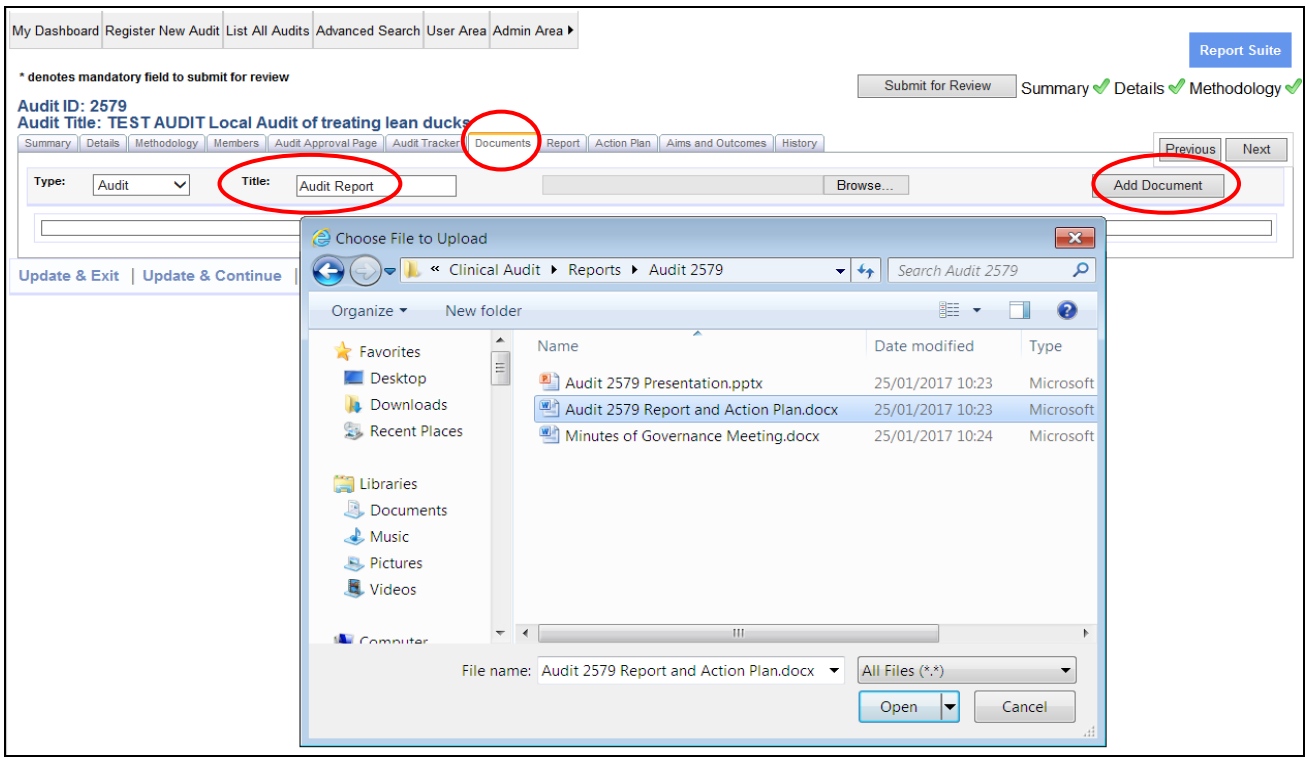
7. Adding members to the project team

All members of the audit team must be listed on this tab so that they can be issued with audit certificates. All staff with a CWP login are listed. Once you have selected a member of staff, please click **'insert'** at the bottom of the page. Always click '**update & continue**' before adding another staff member or leaving the page.



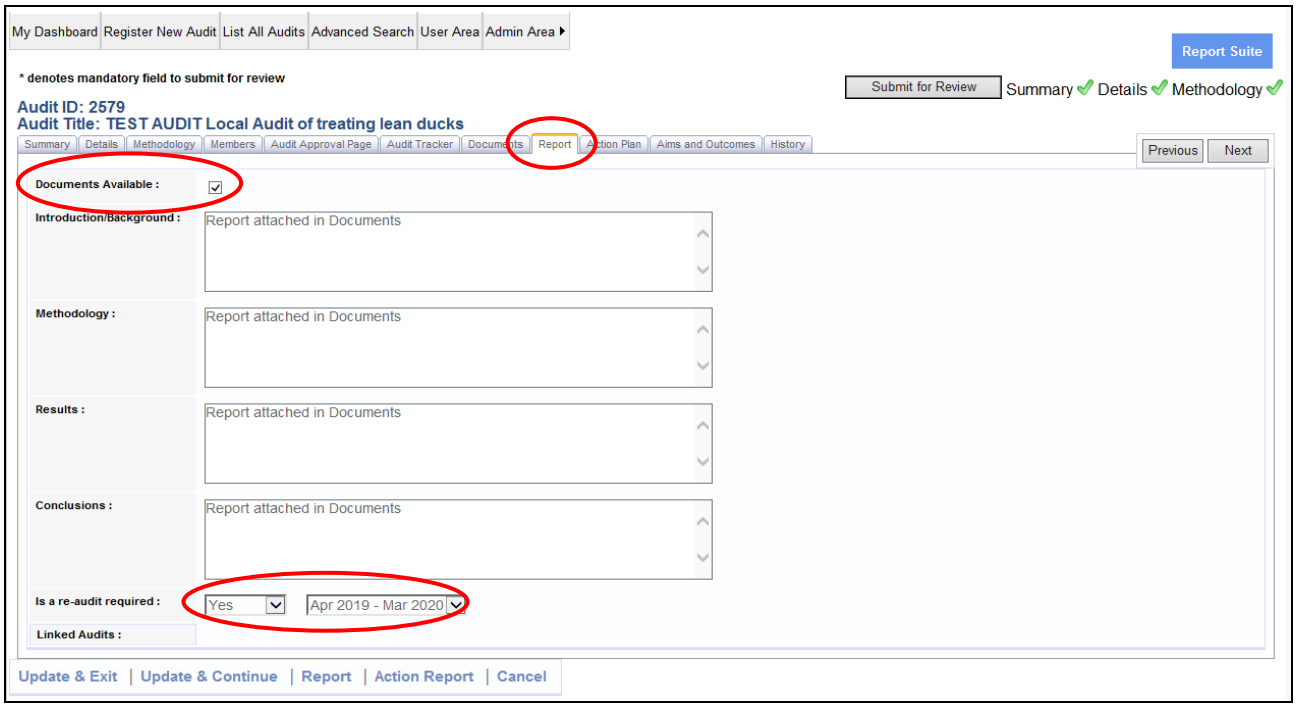
8. Adding documents

The **'document'** tab allows you to upload any relating information to the audit, for example data collection tools, guidance, data analysis, presentations and reports. Complete the **'title'** field, click on **'browse'** to locate the file, and then click **'add document'**.



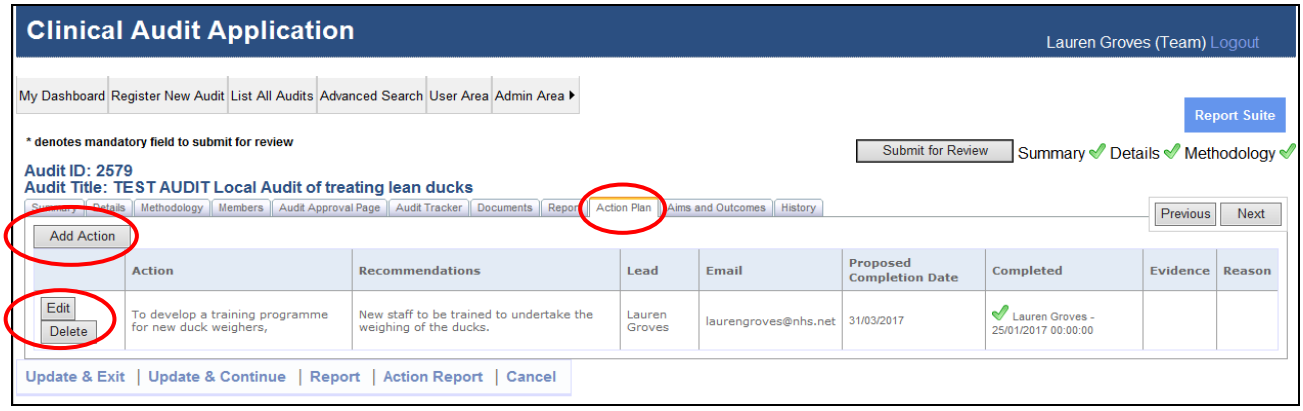
9. Audit reports

Complete all four fields on the Report tab or alternatively tick the '**documents available'** box which will automatically populate the fields with "Report attached in Documents". You will then need to attach a full audit report to the Documents tab (as above). At the bottom of the page, please indicate if the audit requires re-audit and when this will be undertaken.



10. Action plan

Agreed actions must be added to the **'action plan'** tab. Actions must be SMART (Specific, Measurable, Achievable, Realistic and Timely). One recommendation may create several actions; add these as separate lines. Evidence of completed actions should be summarised, and can be attached under the 'Documents' tab (as above) for future reference.

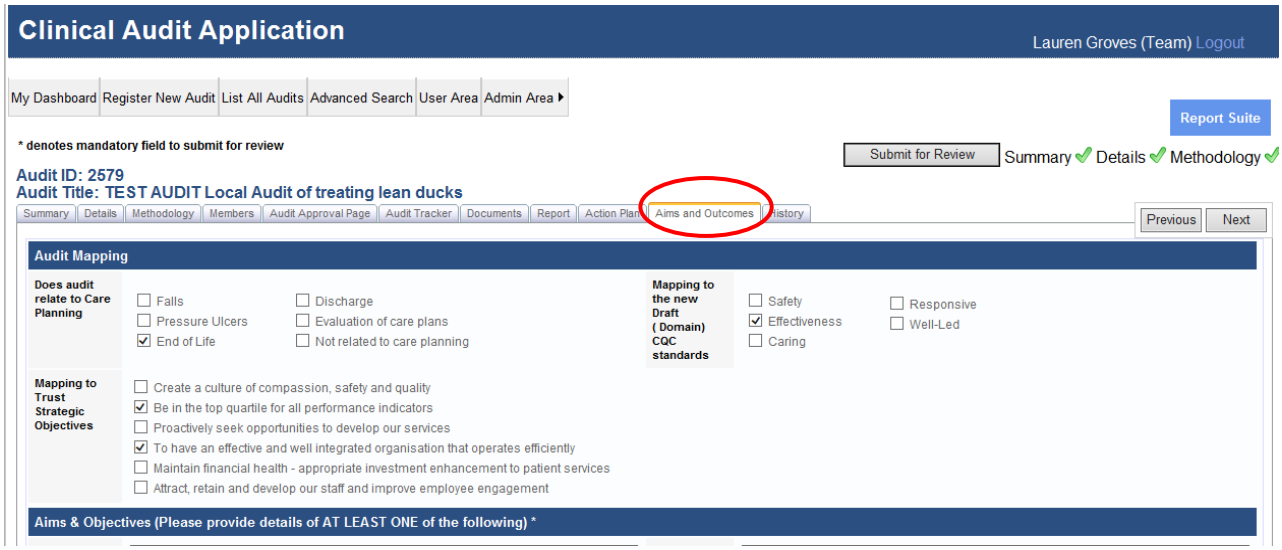


11. Aims & outcomes

The following fields are for the Audit Lead and Audit Convenor to capture compliance against audit standards and the effectiveness of the audit.

Audit mapping

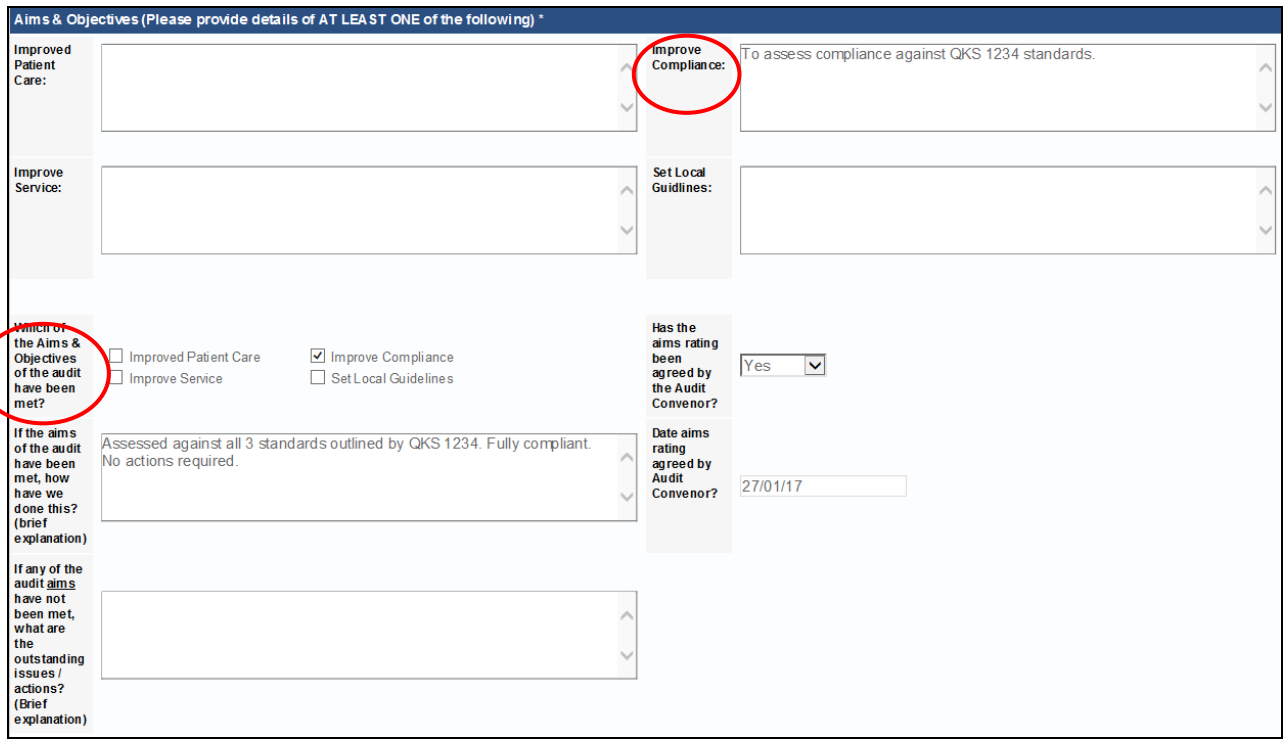
All audits must be mapped to the CQC domains and the trust's strategic objectives. We also indicate whether audits relate to care planning. Tick all appropriate categories (multiple select)



Aims & objectives

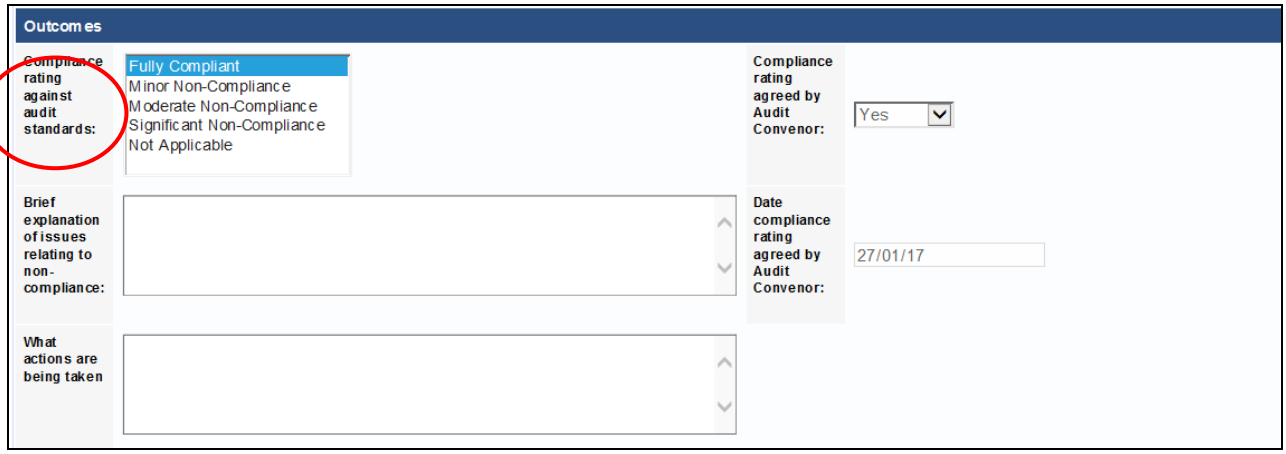
The first part of this section should be populated with the proposed aims/objectives of the audit. Do not put yes/no answers. These will be used later to assess the effectiveness of the audit.

Once your audit has been completed, please check the tick boxes to indicate which aims have been met. Please provide details for a) If the aims of the audit have been met, how was this achieved? b) If the aims were not met, what are the outstanding issues? These will then be agreed by the Directorate Audit Convenor.



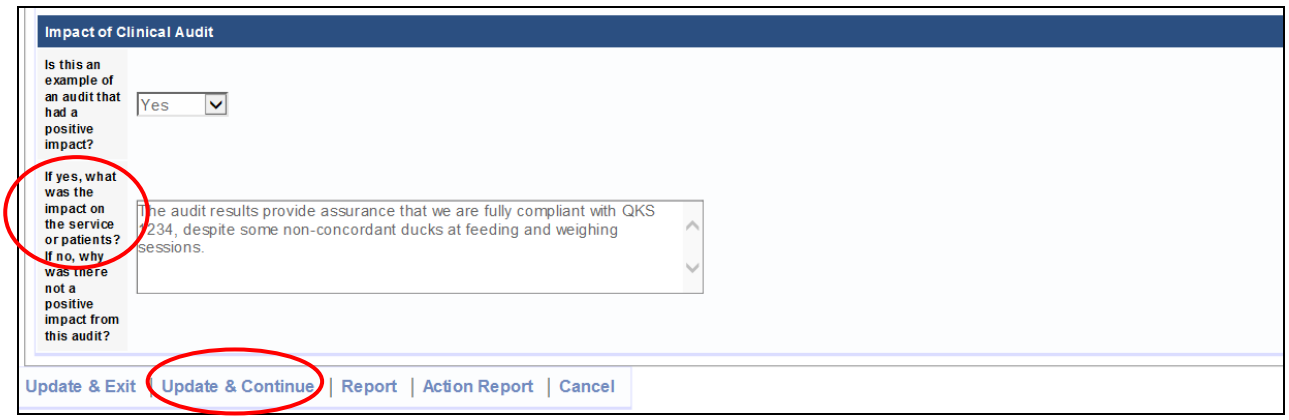
Outcomes

In this section of the aims & outcomes tab we measure compliance against the standards audited. Briefly explain any issues relating to any non-compliance and what actions are being taken to address it. If fully compliant, these boxes should have N/A entered.



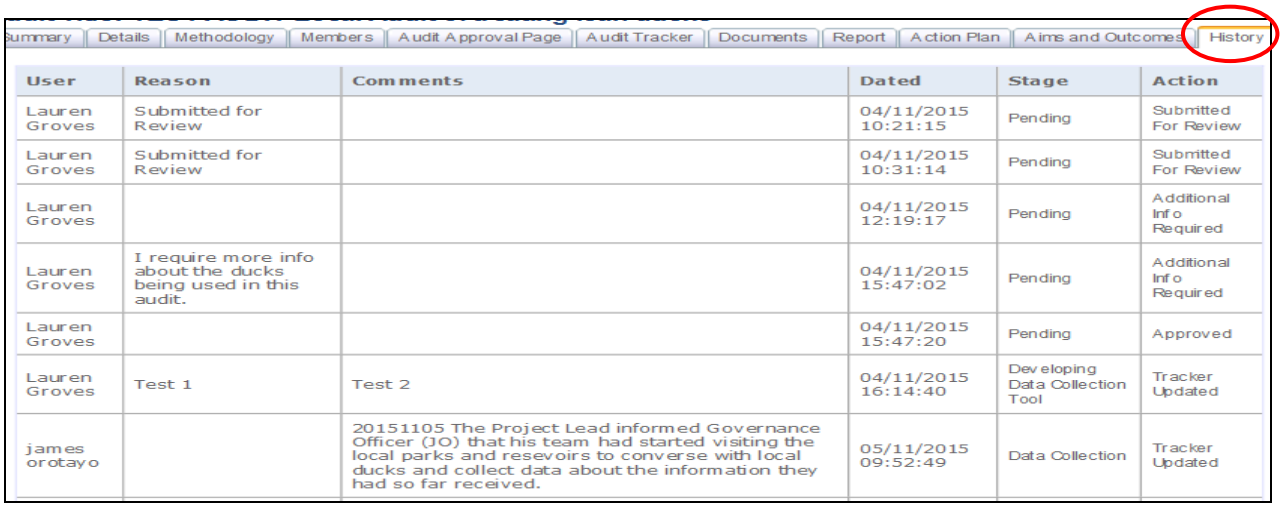
Impact of clinical audit

Please detail the impact the audit has had on patients and/or the service. If there was no impact from this audit, please give reasons why it has been ineffective. You must click **'update & continue'** before moving to the next tab.



12. The history tab

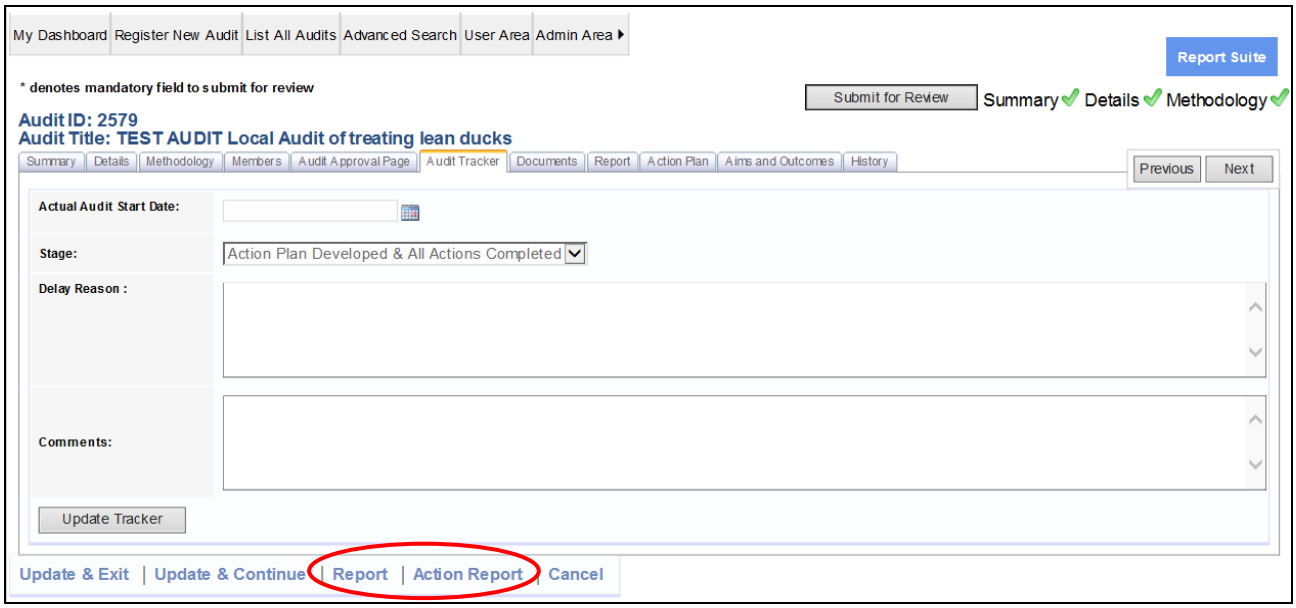
The history tab shows who, what and when the audit project has been updated.



User	Reason	Comments	Dated	Stage	Action
Lauren Groves	Submitted for Review		04/11/2015 10:21:15	Pending	Submitted For Review
Lauren Groves	Submitted for Review		04/11/2015 10:31:14	Pending	Submitted For Review
Lauren Groves			04/11/2015 12:19:17	Pending	Additional Info Required
Lauren Groves	I require more info about the ducks being used in this audit.		04/11/2015 15:47:02	Pending	Additional Info Required
Lauren Groves			04/11/2015 15:47:20	Pending	Approved
Lauren Groves	Test 1	Test 2	04/11/2015 16:14:40	Developing Data Collection Tool	Tracker Updated
james orotayo		20151105 The Project Lead informed Governance Officer (JO) that his team had started visiting the local parks and resevoirs to converse with local ducks and collect data about the information they had so far received.	05/11/2015 09:52:49	Data Collection	Tracker Updated

13. Audit project and action plan Reports

At the bottom of every audit project page, there is a **'report'** option. Click on this to generate an audit project report. The next tab **'action report'** generates the action plan as inputted in to the 'Action Plan' tab (Step 10 above). These can be exported to Word, Excel or PDF format and saved and/or printed as required.



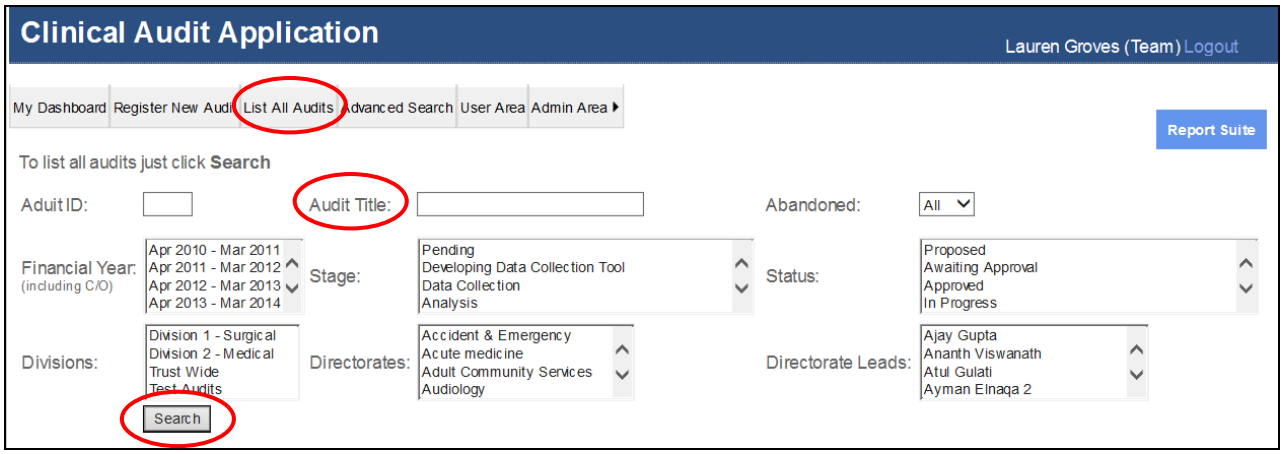
Example reports:

2579 CAD Audit Report.doc

2579 CAD Action Plan.doc

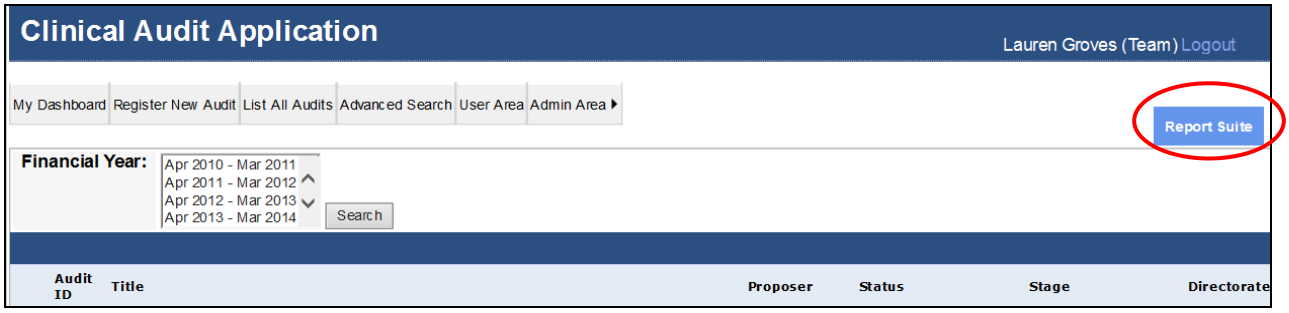
14. Searching for audit projects

The **'list all audits'** tab can be used to search for a particular audit. Here you can search by Audit ID, Title, Financial Year, Division, Directorate, Convenor or Audit Stage/Status. Alternatively, type key words in to the **'audit title'** field and click search to generate a list of audits that contain that word in their title.

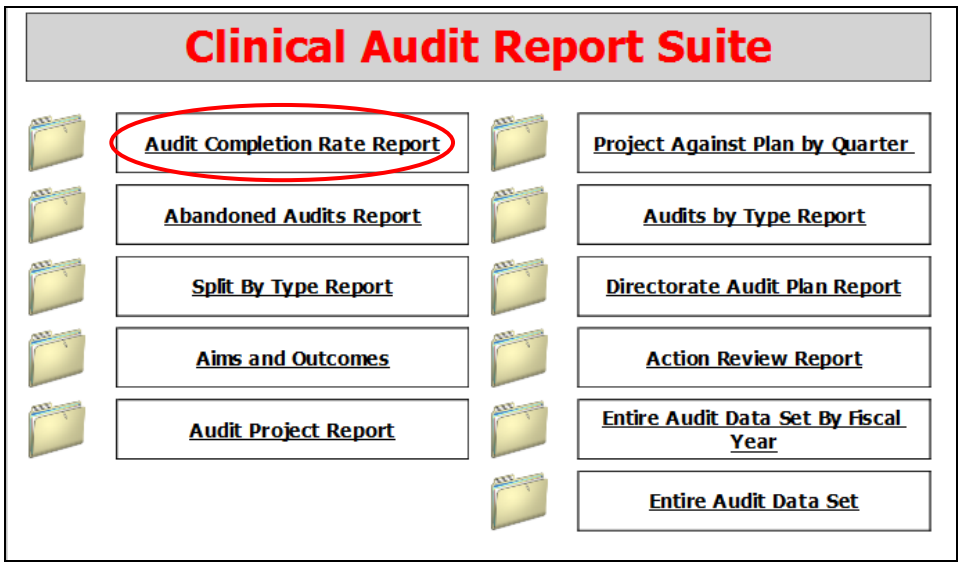


15. The report suite

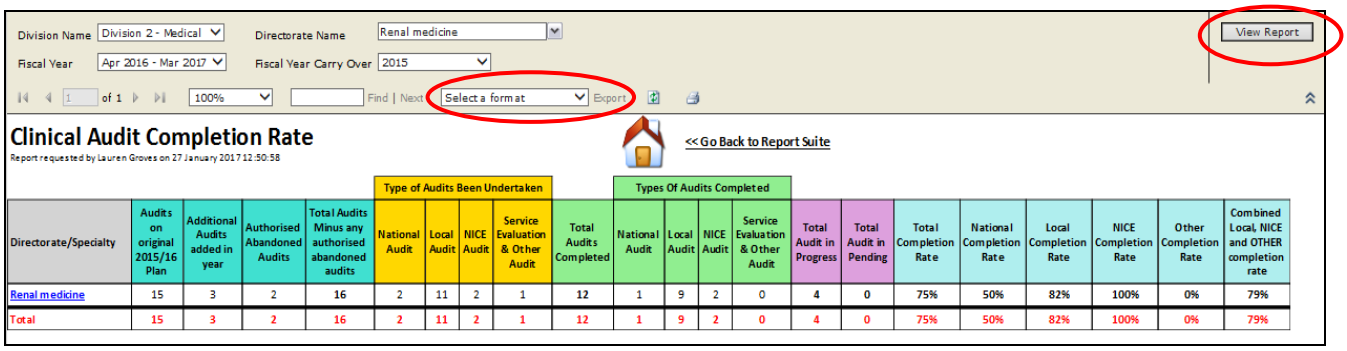
An extended version of CAD is available for Audit Convenors and Governance Officers, which includes access to the Report Suite. Click the **'report suite'** button which will open a new window.



All of the reports are exportable to Word, Excel or PDF format and can be saved and/or printed as required. They are designed to assist Audit Convenors, Governance Officers and Directorate and Divisional Management Teams to assess completion against the agreed annual audit programme. This is a live reporting suite and so any changes to audit projects are reflected immediately in the reports generated.



Click on the report title you wish to produce. For this example, we will generate an 'Audit Completion Rate Report'. Select the Division, Directorate and Fiscal (Audit) Year as required, then click **'view report'**. Carried forward audits are selected automatically. The report can be printed or exported to Word, Excel or PDF format and saved and/or printed as required. All of the above reports are produced using the same format.



Directorate/Specialty	Audits on original 2015/16 Plan	Additional Audits added in year	Authorised Abandoned Audits	Total Audits Minus any authorised abandoned audits	Type of Audits Been Undertaken: National Audit	Local Audit	NICE Audit	Service Evaluation & Other Audit	Total Audits Completed	Types Of Audits Completed: National Audit	Local Audit	NICE Audit	Service Evaluation & Other Audit	Total Audit in Progress	Total Audit in Pending	Total Completion Rate	National Completion Rate	Local Completion Rate	NICE Completion Rate	Other Completion Rate	Combined Local, NICE and OTHER completion rate
Renal medicine	15	3	2	16	2	11	2	1	12	1	9	2	0	4	0	75%	50%	82%	100%	0%	79%
Total	15	3	2	16	2	11	2	1	12	1	9	2	0	4	0	75%	50%	82%	100%	0%	79%

16. Further information

Further training can be requested from the Governance Officer assigned to your Directorate. If problems are encountered, please take a screen shot (press 'print screen' on your keyboard and paste this in to an email) and email this to your Governance Officer to be followed up with IT for resolution.

The Royal Wolverhampton
NHS Trust

New Cross Hospital
Wolverhampton Road
Wolverhampton
West Midlands
WV10 0QP

Tel: 01902 307999

NATIONAL OPT OUT PROCESS FOR CLINICAL AUDIT

Notification of new national audit

GO either receives automatic notification via CAD or via HQIPs National Directory

⇩

Initial Assessment

GO reviews National audits website for applicability. If not available then the audit lead is contacted with a set of standard questions.

⇩

Review

GO reviews the information & makes decision on if Opt Out applies or not and informs TL of decision made and why.

⇩

Final Assessment

TL reviews information provided by GOs and agrees whether Opt Out is applicable.

⇩

Informing & Recording

If Opt Out does not apply TL records on Spread-sheet

If Opt Out does apply then Audit lead are informed by GO and Internal process to follow is provided.

Trouble shooting

- If there remains uncertainty whether the National Opt Out applies after scrutiny of information then IG Enquires will be contacted to advise on this.

Standard questions to be asked to assess applicability

If any of the questions are answered YES then the National Opt Out doesn't apply.

Question	Description
Does this audit ask for explicit patient consent?	This is where we ask the patient if they are willing to participate in the audit- no patient data is entered without consent being first obtained.
Is being provided under S259 (Health and Social Care Act)	The Act gives the Health and Social Care Information Centre (HSCIC) statutory powers, under Section 259 (1), to require data from health or social care bodies or organisations who provide health or adult social care in England.
Is there a local opt out process for patients?	Is there something local in place where we allow patients not to participate e.g. we inform the patient of the audit and they are able to opt out at this stage.
Is the data used in this study anonymised?	Data collected contains no personal identifiers e.g. no names, nhs numbers, hospital IDs etc.