SCIENTIFIC LITERACY AND BASIC CLINICAL RESEARCH

A practical one day course for UK trainees

From critical appraisal to ethical research and publication

Course format	Face to face, highly interactive, beginner to early intermediate
Course duration	09:00 to 17:00, eight hours including breaks
Target group	Foundation doctors, core and higher trainees, clinical fellows and SAS doctors
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COURSE PROPOSAL AND FACULTY HANDBOOK

This document is an educational proposal. Local governance, faculty approval and formal CPD arrangements should be confirmed before delivery.

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Course philosophy

The programme teaches trainees to move from rapid relevance screening to structured critical appraisal. It does not teach them to trust a conclusion because it appears in a prestigious journal. Journal reputation may help identify material, but study design, conduct, analysis, transparency and applicability determine whether an individual paper should influence practice.

1. Executive summary

Scientific Literacy and Basic Clinical Research for UK Trainees is an eight hour, one day programme designed for doctors who have limited formal research training but are expected to practise evidence-based medicine, appraise published literature, participate in research or audit, and contribute to publication. The programme is particularly suitable for surgical trainees, although its principles are transferable to all clinical specialties.

The course is organised around three questions that trainees repeatedly face in clinical practice: How do I read a paper efficiently and safely? How do I write a clear and publishable paper? How do I recognise the strength and limitations of different forms of evidence? These are supported by practical teaching in basic statistics, research design, UK governance, ethical conduct, authorship, reporting guidelines, journal selection and peer review.

The learning is anchored to a realistic surgical example: a retrospective comparative study of total ankle replacement versus ankle arthrodesis. Participants move from a clinical question to a study design, critical appraisal, analysis plan, manuscript structure and submission checklist. The day ends with a completed appraisal worksheet, a one page research plan and a personal action plan.

Course at a glance

Level	Beginner to early intermediate
Delivery	Short lectures, worked examples, small group appraisal, manuscript workshop and guided discussion
Suggested cohort	18 to 24 participants
Educational time	Six hours and forty five minutes of structured teaching within an eight hour day
Participant outputs	Critical appraisal sheet, research design sheet, manuscript outline, post-course action plan
Faculty mix	Clinician researcher, journal editor or experienced reviewer, medical statistician and research governance representative
Portfolio relevance	Evidence-based practice, critical appraisal, basic research principles, research governance and ethics under GPC 9

2. Course rationale and curriculum alignment

Evidence-based practice and research literacy are not optional extras in UK postgraduate medical training. The GMC Generic Professional Capabilities framework includes research and scholarship as Domain 9. Surgical certification guidance groups the expected capabilities into four areas: evidence-based practice, critical appraisal and literature searching, application of basic research principles, and research governance and ethics.[1 to 3]

Many trainees can locate a paper and repeat its conclusion but remain uncertain about whether the study design was appropriate, whether the statistical test answered the stated question, whether bias or confounding altered the result, and whether the findings apply to their patient. A further difficulty arises when trainees are asked to convert a local case series or comparative cohort into a publishable manuscript without a protocol, an analysis plan or familiarity with reporting guidelines.

> **Important correction to a common shortcut**
>
> A busy clinician may begin with the title and abstract to decide whether a paper is relevant. The conclusion may also be scanned during this first pass. However, the conclusion is the authors' interpretation, not an independent test of validity. Before changing practice, the reader must examine the methods and results. A journal impact factor describes a journal level citation average and should not be used as a substitute for appraisal of an individual article.[4]

Alignment with GPC 9

GPC 9 capability	Course content	Participant evidence	Suggested portfolio use
Evidence-based practice	Rapid evidence triage, appraisal of validity, importance and applicability	Completed appraisal worksheet and group presentation	Journal club reflection, CBD or learning event
Critical appraisal and literature review	PICO, searching, study design, risk of bias and evidence hierarchy	Structured critical appraisal and evidence map	Reflective note or journal club evidence
Basic research principles	Question, protocol, outcomes, sample size, data, statistics and reporting	One page research plan and manuscript outline	Research project planning evidence
Governance and ethics	Research versus audit, HRA pathway, consent, confidentiality, authorship and conflicts	Governance checklist and post-course action plan	Course certificate plus reflection

3. Course aims and learning outcomes

Overall aim

To give UK trainees the practical scientific literacy required to read clinical research critically, design and conduct proportionate research safely, and prepare a transparent manuscript for peer-reviewed publication.

Learning outcomes

- Formulate a focused clinical research question using PICO, PECO or an equivalent framework.
- Distinguish systematic reviews, randomised trials, cohort studies, case-control studies, cross-sectional studies, case series, qualitative studies and consensus methods.
- Use a rapid screening process without confusing journal prestige or the authors' conclusion with study validity.
- Appraise selection bias, measurement bias, confounding, random error, missing data, selective reporting and applicability.
- Interpret common effect measures, confidence intervals and p values at a clinically useful introductory level.
- Match a clinical question and data structure to an appropriate broad statistical approach, while recognising when specialist statistical support is required.
- Describe the practical pathway from research idea to protocol, approvals, data collection, analysis and dissemination in the UK.
- Structure an original research paper using IMRaD and select the correct EQUATOR reporting guideline.
- Prepare a journal submission package and respond constructively to peer review.
- Apply current principles of authorship, conflicts of interest, data integrity, patient confidentiality and responsible use of AI assisted tools.

4. One day timetable

The timetable below provides an eight hour course from 09:00 to 17:00. It includes two short refreshment breaks and a forty five minute lunch. The structured educational time is six hours and forty five minutes.

Time	Session	Core content and activity	Participant output
09:00 to 09:15	Welcome and baseline assessment	Course aims, ground rules, ten question pre-course test and identification of participant research needs.	Baseline score and personal learning goal
09:15 to 10:30	1. How to read a paper	Three minute relevance screen, twenty minute critical appraisal, methods, results, bias, effect size, applicability and journal metrics.	Appraisal of an orthopaedic paper
10:30 to 10:45	Refreshment break	Protected break.	None

Time	Session	Core content and activity	Participant output
10:45 to 11:45	2. How to write a paper	IMRaD, drafting order, balanced introduction, reproducible methods, objective results, structured discussion, title and abstract.	Manuscript skeleton
11:45 to 12:30	3. Hierarchy of evidence	Study designs, evidence hierarchy by question type, strengths, limitations, registries, case series and Delphi consensus.	Evidence hierarchy map
12:30 to 13:15	Lunch	Protected lunch.	None
13:15 to 14:00	4. Basic statistics without fear	Data types, descriptive statistics, common tests, effect estimates, confidence intervals, p values, sample size and common errors.	Analysis choice worksheet
14:00 to 15:00	5. Conducting a clinical study	Question, protocol, team, outcomes, approvals, data collection, quality assurance, analysis plan and reporting guideline.	One page mini protocol
15:00 to 15:15	Refreshment break	Protected break.	None
15:15 to 16:00	6. Governance, ethics and authorship	Research versus audit, HRA and REC pathways, confidentiality, consent, authorship, conflicts, misconduct and AI assisted tools.	Governance checklist
16:00 to 16:45	7. Publication and peer review workshop	Target journal, instructions for authors, cover letter, reporting checklist, reviewer response and avoiding predatory journals.	Submission checklist and reviewer response
16:45 to 17:00	Assessment and close	Post-course test, answer review, personal action plan, feedback and certification process.	Post-course score and action plan

5. Detailed session plans

Session 1. How to read a paper efficiently and critically

Duration: 75 minutes

Learning objectives:

- Separate relevance screening from quality appraisal.
- Identify the research question, design, population, intervention or exposure, comparator and outcomes.
- Decide whether methods are sufficiently valid before accepting the authors' interpretation.
- Summarise the result using effect size, precision, harms and applicability.

Core content: A two-stage approach is taught. Stage one is a rapid screen of the title, abstract, question, study type, date and clinical relevance. Stage two is a structured appraisal of methods, results, risk of bias and applicability. The session explains why the methods and results must be reviewed before the conclusion is trusted. Journal reputation, indexing and editorial standards are discussed as context rather than proof of quality.

Practical activity: Small groups appraise a comparative orthopaedic study and give a sixty second verdict: trustworthy, uncertain or not practice changing, with reasons.

Suggested faculty: Clinician researcher and journal editor or experienced reviewer.

Session 2. How to write a paper that can be understood and reviewed

Duration: 60 minutes

Learning objectives:

- Use IMRaD as a reporting structure.
- Write a focused introduction that identifies the knowledge gap and study objective.
- Describe methods in enough detail to permit appraisal and replication.
- Separate results from interpretation and write a proportionate conclusion.

Core content: The course distinguishes publication structure from drafting order. A practical sequence is: finalise the question and protocol, write the methods early, complete tables and results after analysis, then write the introduction and discussion, and write the title and abstract last. Participants learn the three paragraph introduction, the reproducible methods checklist, an objective results sequence and a six-part discussion. A narrative introduction is not a systematic review, but it must still be balanced and must not cherry-pick only supportive evidence.

Practical activity: Participants convert an ankle replacement versus ankle arthrodesis project into a one page manuscript skeleton.

Suggested faculty: Senior author or journal editor.

Session 3. Hierarchy of evidence and study design

Duration: 45 minutes

Learning objectives:

- Recognise common clinical study designs.
- Use an evidence hierarchy as a starting point rather than an automatic verdict.
- Understand why the best design depends on the clinical question.
- Describe the role and limitations of formal expert consensus.

Core content: For treatment benefit, a high quality systematic review of suitable randomised trials usually sits near the top of the hierarchy. However, hierarchy changes with questions of diagnosis, prognosis, harms, implementation and patient experience. Participants learn that a poor systematic review can be less trustworthy than a well conducted primary study. The Delphi technique is introduced as a structured, iterative consensus method used when evidence is limited or when agreement is itself the research objective, not as a substitute for comparative effectiveness evidence.

Practical activity: Groups place eight example studies in an evidence map and explain where quality might move a study up or down.

Suggested faculty: Clinician epidemiologist or methodologist.

Session 4. Basic statistics without fear

Duration: 45 minutes

Learning objectives:

- Identify continuous, categorical, ordinal and time-to-event data.
- Recognise common tests and the questions they address.
- Interpret effect sizes, confidence intervals and p values together.
- Identify situations requiring a statistician.

Core content: The aim is scientific literacy rather than manual calculation. Participants learn how data type, independence, pairing, distribution, repeated measurements and confounding influence analysis. Common problems include multiple testing, small samples, missing data, inappropriate use of means, failure to account for pairing or clustering, overfitted regression and reporting p values without effect estimates or confidence intervals.

Practical activity: Participants match six clinical questions to suitable broad analyses and state what should be reported.

Suggested faculty: Medical statistician or quantitatively experienced researcher.

Session 5. Conducting a clinical study from idea to dataset

Duration: 60 minutes

Learning objectives:

- Convert a clinical problem into a feasible research question.
- Choose a proportionate design, outcomes and analysis plan.
- Identify the team, approvals, data sources and quality controls required.
- Recognise the difference between confirmatory and exploratory work.

Core content: Participants work through a twelve-step research pathway from question to dissemination. Particular attention is given to defining the primary outcome before analysis, involving a statistician early, choosing validated patient-reported outcome measures, managing missing data, documenting inclusion and exclusion, and distinguishing pre-specified analyses from exploratory findings.

Practical activity: Each participant writes a one page mini protocol for a project they could realistically undertake in their department.

Suggested faculty: Clinician researcher and statistician.

Session 6. UK governance, ethics, authorship and research integrity

Duration: 45 minutes

Learning objectives:

- Distinguish research from audit and service evaluation.
- Identify when sponsor, HRA, REC or local approvals may be required.
- Apply basic principles of consent, confidentiality, data protection and transparency.
- Use authorship and contributor criteria responsibly.

Core content: The session uses the current UK Policy Framework for Health and Social Care Research and HRA decision tools. It also covers protocol deviations, data fabrication and falsification, plagiarism, duplicate submission, conflicts of interest, patient consent for identifiable material, and responsible use of AI assisted technology. Trainees are reminded that authors remain accountable for accuracy and confidentiality.

Practical activity: Groups classify four example projects and identify the next governance action for each.

Suggested faculty: Research and development or governance representative, with senior researcher.

Session 7. Preparing for publication and peer review

Duration: 45 minutes

Learning objectives:

- Select a legitimate journal by scope and editorial standards.
- Prepare the manuscript, checklist, declarations and cover letter.
- Respond to reviewers clearly and professionally.
- Recognise predatory or pseudo-journals.

Core content: Journal selection is based on fit, readership, indexing, transparency, editorial policies, publication model and realistic acceptance prospects. Impact factor is discussed as one contextual metric, not a guarantee of article quality. Participants review a submission package and practise a point-by-point reviewer response that identifies each comment, states the action taken, gives revised text and explains respectfully when a change is not made.

Practical activity: Participants edit a weak cover letter and one poor reviewer response.

Suggested faculty: Journal editor or experienced peer reviewer.

6. Core teaching framework: how to read a paper

6.1 Two-stage reading model and optional deep read

Stage	Purpose	What to read	Decision
Stage 1: three minute relevance screen	Decide whether the paper deserves further time.	Title, abstract, clinical question, study design, population, date, journal scope and declared funding.	Relevant now, save for later, or reject as irrelevant.
Stage 2: twenty minute critical appraisal	Decide whether the result can be trusted and applied.	Methods first, then results, then discussion and conclusion. Check protocol or supplement if important.	Trustworthy, uncertain, or not sufficiently valid.

Stage	Purpose	What to read	Decision
Stage 3: deep read for practice change or research	Understand detail, reproduce methods, or prepare a guideline, protocol or manuscript.	Full paper, supplementary files, protocol, statistical analysis plan, related literature and reporting checklist.	Use, use cautiously, or do not use. Record reasons.

6.2 Recommended appraisal sequence

No.	Appraisal domain	Key question
1	Question	What clinical question is being asked? Is it focused and relevant?
2	Design	Can this design answer that question? Is a comparator present when one is needed?
3	Population	Who was included, excluded and lost to follow-up? Is selection likely to bias the result?
4	Intervention or exposure	Was it clearly defined and delivered consistently?
5	Comparator	Is it appropriate, contemporary and treated similarly apart from the exposure of interest?
6	Outcomes	Were outcomes clinically important, validated, pre-specified and measured similarly in all groups?
7	Bias and confounding	What could systematically distort the estimate? Was adjustment appropriate?
8	Statistics	Does the analysis match the data, design and unit of analysis? How were missing data handled?
9	Results	What is the magnitude and precision of the effect? What happened to harms and missing participants?
10	Applicability	Are the patients, setting, intervention and outcomes sufficiently similar to local practice?
11	Interpretation	Does the discussion acknowledge limitations and does the conclusion stay within the data?

6.3 The sixty second paper verdict

At the end of appraisal, the trainee should be able to state the following in no more than sixty seconds:

- The clinical question and study design.
- The main result expressed as an effect size with uncertainty, not only a p value.
- The two most important strengths.
- The two most important threats to validity.
- Whether the findings apply locally.
- Whether the paper should change practice, support discussion, or prompt further research.

> **What not to do**
>
> Do not assume that a paper is valid because it is published in a high impact journal. Do not accept a systematic review simply because it contains a meta-analysis. Do not treat statistical significance as clinical importance. Do not ignore absolute effects, harms, missing data or the comparator.

7. Core teaching framework: how to write a paper

7.1 IMRaD is the reporting structure, not necessarily the drafting order

A publishable original research paper usually follows Introduction, Methods, Results and Discussion, followed by a concise conclusion where the journal requires one. The abstract is normally written last. Many authors find the following drafting sequence more reliable because it keeps the paper anchored to what was planned and what was actually found:

1. Define the question, primary outcome, design and analysis plan before examining the final results.
2. Write and preserve the Methods while the protocol and conduct are clear.
3. Clean the dataset, complete the analysis and finalise tables and figures.
4. Write the Results directly from the final tables without interpretation.
5. Write the Introduction to establish the clinical problem, current knowledge, gap and objective.
6. Write the Discussion to interpret the principal findings in context.
7. Write the Conclusion, title and abstract last, ensuring that each matches the data.

7.2 A practical structure for each section

Section	Purpose	Recommended structure	Common errors
Title and abstract	Allow accurate discovery and rapid understanding.	Name the design where useful. State objective, methods, main numerical results and proportionate conclusion.	Vague title, unstructured abstract, no effect size, conclusion stronger than results.
Introduction	Explain why the study was needed.	Paragraph 1: clinical problem. Paragraph 2: current evidence and gap. Paragraph 3: objective and hypothesis.	Long history, unsupported claims, selective citation, presenting results in advance.
Methods	Allow appraisal and replication.	Design, setting, dates, participants, eligibility, interventions or exposures, comparator, outcomes, sample size, statistics, ethics and registration.	Missing primary outcome, unclear cohort formation, statistics added after results, no missing data plan.
Results	Report what was found objectively.	Participant flow, baseline data, primary outcome, secondary outcomes, harms, missing data and sensitivity analyses.	Repeating every table, interpretation, selective outcomes, p values without estimates and confidence intervals.
Discussion	Interpret findings in context.	Principal finding, comparison with literature, possible explanations, strengths, limitations, implications and next research step.	Restating results, claiming causality from association, hiding limitations, unbalanced citation.
Conclusion	Provide the most defensible take-home message.	Answer the objective at the level supported by design and precision.	Practice recommendation unsupported by evidence, absolute language, new results.

7.3 Narrative introduction versus systematic review

The introduction to an original retrospective study is a focused narrative account, not a systematic review. The author is therefore not required to perform a full systematic review merely to write the introduction. However, the author should search sufficiently to identify major reviews, guidelines, landmark studies and credible contradictory evidence. Selective citation designed to manufacture a gap is poor scientific practice. The search approach and key evidence should be documented within the research file even when a PRISMA review is not being conducted.

7.4 Reporting guidelines

Study type	Principal guideline	How it is used
Randomised trial	CONSORT 2025	Use during protocol development and manuscript drafting. Include participant flow and all required items.[8]

Study type	Principal guideline	How it is used
Randomised trial protocol	SPIRIT 2025	Use to make the protocol complete, transparent and prospectively usable.
Cohort, case-control or cross-sectional study	STROBE	Use for transparent reporting of observational design, participants, variables, bias and analysis. [9]
Systematic review or meta-analysis	PRISMA 2020	Use for search, selection, risk of bias, synthesis and flow reporting.[10]
Case report	CARE	Use for clinical timeline, diagnostic reasoning, intervention, outcomes and patient perspective where appropriate.[11]
Diagnostic accuracy study	STARD	Use for index test, reference standard, participant flow and accuracy estimates.
Prediction model	TRIPOD	Use for model development, validation and transparent reporting.
Consensus study	ACCORD or appropriate Delphi guidance	Report panel selection, evidence base, rounds, anonymity, feedback, consensus definition and disagreement.[16]

8. Hierarchy of evidence and study designs

The hierarchy below is a practical teaching model for questions about treatment benefit. It is not a universal ranking for every research question. Diagnostic accuracy, prognosis, harms, patient experience, implementation and health economics require different optimal designs. The Oxford Centre for Evidence-Based Medicine explicitly advises that levels of evidence are a shortcut requiring judgement, not a substitute for appraisal.[5,6]

Approximate place for treatment benefit	Design	Best contribution	Main threats	Typical reporting tool
Highest when well conducted	Systematic review, with or without meta-analysis, of suitable high quality trials	Synthesises the complete relevant evidence and explores consistency.	Poor search, selective inclusion, high risk of bias in included studies, inappropriate pooling and publication bias.	PRISMA 2020
High	Randomised controlled trial	Estimates causal treatment effects by balancing known and unknown prognostic factors on average.	Poor allocation concealment, lack of blinding where feasible, crossover, loss to follow-up, selective outcomes and inadequate power.	CONSORT 2025
Moderate	Prospective comparative cohort or high quality registry study	Studies prognosis, safety, effectiveness and real world practice when randomisation is unavailable.	Confounding by indication, selection, treatment crossover, missing data and outcome ascertainment.	STROBE
Moderate to low	Retrospective comparative cohort	Uses existing records to compare outcomes efficiently and generate or test hypotheses.	Incomplete records, non-contemporary comparator, selection, misclassification, confounding and missing data.	STROBE or specialty extension
Variable	Case-control study	Efficiently studies uncommon outcomes or long latency problems.	Control selection, recall or recording bias, temporality and confounding.	STROBE
Variable	Cross-sectional study	Estimates prevalence and examines associations at one time point.	No clear temporality, selection and measurement bias.	STROBE
Low for comparative effectiveness	Case series or case report	Describes feasibility, novel observations, rare complications or early safety signals.	No comparator, selection, regression to the mean and inability to estimate causal effect.	CARE for case reports

Approximate place for treatment benefit	Design	Best contribution	Main threats	Typical reporting tool
Consensus rather than direct comparative evidence	Delphi, formal consensus or expert opinion	Defines priorities, terminology or recommendations where evidence is incomplete and agreement is the objective.	Panel selection, unclear evidence base, attrition, dominant framing and arbitrary consensus thresholds.	ACCORD or Delphi guidance
Different dimension, not simply low	Qualitative research	Explores patient experience, acceptability, implementation, context and meaning.	Sampling, reflexivity, analytic transparency and transferability.	COREQ or SRQR

8.1 Key teaching points about the hierarchy

- A systematic review is only as trustworthy as its methods and included evidence.
- Meta-analysis is a statistical technique and is not automatically appropriate or superior.
- Randomisation reduces confounding on average but does not protect against every source of bias.
- A prospective registry can be extremely valuable, but prospective data collection does not itself remove confounding.
- A control group should be appropriate, comparable and contemporary whenever the research question requires comparison.
- Case reports and case series remain important for novelty and rare harms, but they cannot reliably establish comparative effectiveness.
- Delphi consensus is a research method for structured judgement. It should report panel selection, rounds, feedback, attrition and the definition of consensus.
- The correct design depends first on the question, then on feasibility and ethics.

9. Basic statistics for clinical trainees

The statistical session teaches trainees to ask the correct questions and recognise inappropriate analysis. It does not attempt to replace formal statistical training or specialist advice. A statistician should ideally be involved before data collection and certainly before an unfamiliar or high stakes analysis is finalised.

Clinical question	Data structure	Common introductory method	Report	Common error
Compare a continuous outcome between two independent groups	Continuous, independent	Independent t test if assumptions are reasonable, or a suitable non-parametric alternative	Group summaries, mean or median difference and 95% confidence interval	Choosing the test only from a normality p value or reporting only p
Compare preoperative and postoperative scores in the same patients	Continuous or ordinal, paired	Paired t test or Wilcoxon signed-rank test	Paired change with uncertainty and number of complete pairs	Treating observations as independent
Compare complication proportions	Binary outcome	Chi square or Fisher exact test	Absolute risks, risk difference or risk ratio, and 95% confidence interval	Reporting only odds ratio or p value when absolute risk is clinically clearer
Estimate association while adjusting for confounders	Outcome plus several predictors	Linear, logistic or other regression appropriate to outcome	Adjusted effect estimates, uncertainty and model specification	Too many predictors for the sample, data-driven variable selection, no assessment of assumptions
Analyse time to revision or reoperation	Time-to-event with censoring	Kaplan-Meier and Cox regression where appropriate	Survival estimates, hazard ratio and confidence interval	Ignoring different follow-up times or treating censoring as no event
Analyse repeated follow-up measurements	Repeated or clustered data	Mixed effects or generalised estimating approach	Time effect, group effect, interaction and uncertainty	Multiple separate tests or ignoring within-patient correlation
Assess agreement between measurements	Paired measurements of same quantity	Bland-Altman analysis or intraclass correlation as appropriate	Bias, limits of agreement and clinical acceptability	Using correlation alone to claim agreement
Explore more than one outcome or subgroup	Multiple hypotheses	Pre-specification, multiplicity strategy and cautious exploratory interpretation	Number of analyses and distinction between confirmatory and exploratory	Selective reporting of significant findings

9.1 Five statistical messages every trainee should retain

- Effect size answers how large the difference or association is.
- A confidence interval expresses the range of estimates most compatible with the data and model assumptions.
- A p value does not measure the size, clinical importance or probability that the hypothesis is true.
- Statistical significance can coexist with trivial clinical benefit, and clinically important uncertainty can coexist with a non-significant result.
- The analysis must respect the design, unit of analysis, pairing, clustering, follow-up and missing data.

10. Conducting research in the United Kingdom

10.1 The twelve-step research pathway

Step	Action	Practical requirement
1	Identify the problem	Start with an uncertainty that matters to patients, clinicians or the service.
2	Formulate the question	Use PICO for interventions, PECO for exposures, or another design-appropriate framework.
3	Review existing evidence	Find current guidelines, systematic reviews, landmark studies, ongoing trials and contradictory evidence.
4	Choose the design	Match design to the question, ethical constraints, feasible recruitment, available data and required comparator.
5	Define outcomes and analysis before data review	Specify the primary outcome, time point, clinically important difference, covariates and planned sensitivity analyses.
6	Build the team	Agree chief or principal investigator responsibilities, clinical expertise, statistics, data management, patient involvement and authorship expectations.
7	Classify the project	Use the HRA decision tool and local research and development advice to distinguish research, audit, service evaluation and other activity. [12,13]
8	Obtain approvals and sponsorship	Confirm sponsor, HRA or REC review where applicable, local capacity and capability, information governance and contracts before starting.
9	Create secure data systems	Use a data dictionary, unique identifiers, access controls, audit trail, data quality checks and a retention plan.
10	Conduct according to protocol	Document recruitment, eligibility, consent where applicable, deviations, adverse events, follow-up and missing data.
11	Analyse transparently	Follow the plan, preserve a reproducible record, label exploratory analyses and report all relevant outcomes.
12	Report and disseminate	Use the correct reporting guideline, write for the intended audience, publish negative or uncertain results and communicate findings to participants and services where appropriate.

10.2 Research, audit and service evaluation

Trainees should not classify a project solely by the intention to publish. A project may be publishable and still be audit or service evaluation, while a retrospective record review may meet the definition of research. Classification depends on the

purpose, design, allocation of interventions, generalisability and other features. The HRA decision tools and local research governance team should be used before data collection begins.[12,13]

Activity	Primary purpose	Typical comparison	Governance message
Research	Generate new, generalisable knowledge using a defined protocol.	May compare interventions, exposures or diagnostic strategies.	May require sponsor, HRA approval, REC review and local confirmation depending on study.
Clinical audit	Measure current care against an explicit standard and improve practice.	Current practice versus standard, often followed by re-audit.	Usually managed through local clinical governance, but data protection and approvals still apply.
Service evaluation	Judge how well a local service is working without creating a new research intervention.	Service performance against local objectives or alternatives.	Usually local governance route. Seek advice where classification is uncertain.

11. Publication, peer review and research integrity

11.1 Choosing a journal

- Match the topic and article type to the journal's scope and readership.
- Check indexing, publisher identity, editorial board, peer review process, fees, archiving and transparent policies.
- Read recent papers to judge fit, style and methodological expectations.
- Use journal impact metrics only as contextual information, never as a substitute for article level appraisal.[4]
- Avoid journals that promise guaranteed acceptance, conceal fees, imitate legitimate titles or provide unverifiable editorial information.[14]

11.2 Submission package

Item	What it should contain	Final check
Manuscript	Journal format, complete sections, line numbers where requested, consistent tables and figures.	Objective, methods, results and conclusion agree.
Title page	Authors, affiliations, corresponding author, word count and declarations required by the journal.	Names and order approved by all authors.
Reporting checklist	Completed guideline checklist with page references.	Correct guideline and extension selected.
Cover letter	Why the paper matters, why it fits the journal, originality and required declarations.	No exaggerated claims or generic text.
Ethics and governance statement	Approval, waiver or classification, consent and registration as applicable.	Identifiers and dates accurate.
Authorship and contributions	ICMJE authorship criteria and contributorship roles where requested.[15]	All authors meet criteria and accept accountability.
Conflicts and funding	Financial and non-financial relationships, funder role and support.	Consistent across submission system and manuscript.
Data and AI statements	Data availability and transparent disclosure of AI assisted technology where journal policy requires.	No confidential or identifiable material entered into an unauthorised system.

11.3 Responding to reviewers

A strong response document is respectful, complete and easy to audit. Copy each reviewer comment, state the action taken, quote or summarise the revised text, and identify its location. Where the authors disagree, explain the scientific reason, acknowledge the reviewer's concern and improve the manuscript where possible. Never dismiss a comment merely because the reviewer has misunderstood the paper, because misunderstanding often signals that the manuscript is unclear.

Reviewer comment	Paste the full comment.

Response	Thank the reviewer, answer directly and state the decision.
Change made	Describe the exact change or justify why no change was made.
Revised text	Quote the new text when practical.
Location	Provide page, paragraph and line numbers.

11.4 Research integrity and AI assisted tools

Current ICMJE recommendations address authorship, conflicts of interest, participant protection, reporting, peer review, duplicate publication, journal integrity and AI assisted technology.[14,15] The course should teach the following minimum rules:

- A human author remains responsible for every statement, reference, analysis and conclusion.
- AI tools do not meet authorship criteria and should not be listed as authors.
- Use of AI assisted technology should be disclosed when required by the journal and described accurately.
- Do not place identifiable patient information, confidential manuscripts, unpublished data or reviewer material into an unapproved public system.
- Verify generated references and quotations against the original source.
- Fabrication, falsification, plagiarism, hidden duplicate publication and selective outcome reporting are unacceptable.

12. Assessment, certification and portfolio evidence

12.1 Assessment strategy

Assessment	Timing	Purpose	Evidence retained
Ten question pre-course test	09:00	Establish baseline knowledge and focus teaching.	Anonymous aggregate score or individual result.
Observed group appraisal	Session 1	Assess use of structured appraisal and ability to justify a verdict.	Completed appraisal worksheet.
Analysis choice worksheet	Session 4	Assess recognition of data structure and broad test choice.	Marked worksheet with corrections.
One page mini protocol	Session 5	Assess question, design, outcomes, governance and feasibility.	Participant project plan.
Ten question post-course test and action plan	16:45	Measure immediate learning and identify next steps.	Post-course result and signed action plan.

Suggested completion requirements: full attendance apart from agreed exceptional circumstances, active participation in the appraisal and protocol exercises, and completion of the post-course assessment and action plan. A certificate should confirm attendance and completion, not independent competence in research methodology. Formal CPD accreditation, if sought, should be obtained through the relevant local or professional process.

12.2 Suggested ISCP portfolio package

- Certificate of attendance and course programme.
- Completed critical appraisal worksheet.
- One page mini protocol or manuscript plan.
- A short reflection explaining how the course will change journal club, clinical decision making or a current research project.
- Optional linked CBD, journal club presentation, audit, quality improvement or research activity.

13. Faculty, facilities and course resources

13.1 Suggested faculty

Faculty role	Contribution	Suggested staffing
Course director	Overall design, clinical integration, facilitation and quality assurance.	One senior clinician researcher.
Journal editor or senior reviewer	Writing, journal selection, peer review and publication standards.	One invited faculty member, for example an editor or editorial board member from a relevant journal such as Injury.
Medical statistician	Basic statistics, analysis planning and worked examples.	One statistician or clinician with advanced quantitative expertise.
Research governance representative	HRA pathway, ethics, sponsorship, information governance and local process.	One research and development or governance professional.
Small group facilitators	Support appraisal and protocol workshops.	Aim for approximately one facilitator per eight to ten participants.

13.2 Facilities and materials

- Room arranged for both plenary teaching and groups of four to six.
- Projection, reliable internet access and flip charts or whiteboards.
- Pre-selected clinical paper, preferably one RCT and one observational study, distributed at least seven days in advance.
- Participant handbook containing the timetable, appraisal worksheet, statistics table, mini protocol, reporting guideline map and submission checklist.
- Access to CASP or CEBM appraisal tools, EQUATOR reporting guidelines, HRA decision tools and ICMJE recommendations.
- Optional anonymised dataset or results table for the statistics exercise.

13.3 Pre-course preparation

- Read the title and abstract of the selected paper and write one sentence describing the clinical question.
- Bring one clinical uncertainty or research idea from current practice.
- Complete a short online baseline survey covering prior publications, statistical confidence and governance experience.
- Do not require prior statistical software knowledge.

13.4 Post-course development

The one day course should be viewed as an entry point. A sustainable programme can add a monthly structured journal club, a quarterly protocol clinic, access to a statistician, peer writing groups and supervised involvement in an active departmental project. Participants may be invited to submit their revised mini protocol within four weeks for brief faculty feedback.

14. Appendices

Appendix 1. Rapid critical appraisal worksheet

Paper title: _____

Citation: _____

Clinical question in one sentence: _____

Domain	Questions to answer	Notes or verdict
Relevance	Is the population, intervention or exposure, comparator and outcome relevant to my question?	

Domain	Questions to answer	Notes or verdict
Design	Is the design appropriate for the stated objective?	
Selection	How were participants identified? Who was excluded or lost?	
Comparator	Is the control or comparison group appropriate and contemporary?	
Outcomes	Are the outcomes important, valid, pre-specified and measured consistently?	
Bias	What are the main risks of selection, measurement, performance or reporting bias?	
Confounding	Could group differences explain the result? Was adjustment sensible?	
Statistics	Does the analysis match the design and data? Were missing data and repeated measures handled?	
Results	What is the effect size and 95% confidence interval? What happened to harms?	
Applicability	Would my patients, setting and treatment pathway differ materially?	
Conclusion	Does the conclusion match the design, results and uncertainty?	
Overall verdict	Trustworthy, uncertain or not sufficiently valid? Would it change practice?	

Appendix 2. One page research and manuscript planning sheet

Working title	
Clinical problem	
Research question	
Study design	
Population and setting	
Intervention or exposure	
Comparator	

Primary outcome and time point	
Secondary outcomes and harms	
Sample size or available cohort	
Main sources of bias and confounding	
Planned statistical approach	
Governance route and approvals	
Reporting guideline and target journal	
Proposed authors and contributions	

Appendix 3. Manuscript final check before submission

No.	Check	Done
1	The objective, primary outcome and conclusion are consistent across the abstract and main text.	☐
2	The study design is named accurately and the dates and setting are clear.	☐
3	Eligibility, cohort formation and participant flow can be reconstructed by the reader.	☐
4	All outcomes and analyses are labelled as pre-specified or exploratory where appropriate.	☐
5	Effect estimates and confidence intervals are reported, with p values used appropriately.	☐
6	Tables and figures add information rather than duplicate the text.	☐
7	Limitations include the most important threats to validity and applicability.	☐
8	The appropriate reporting guideline has been completed.	☐
9	Ethics, governance, consent, registration, funding, conflicts and data availability are stated correctly.	☐
10	Every author has approved the final version, meets authorship criteria and accepts accountability.	☐
11	References have been checked against original sources.	☐

No.	Check	Done
12	The journal's instructions, word count, file types and submission declarations have been followed.	☐

15. References and core resources

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> **Faculty note**
>
> Before each course delivery, faculty should check whether national guidance, reporting statements, journal requirements or local research governance pathways have changed. The document should then be version controlled and updated.