



# STAT8608

## Clinical Biostatistics

Session 1, Fully online/virtual 2020

*Department of Mathematics and Statistics*

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## General Information

Unit convenor and teaching staff
Credit points 10
Prerequisites ((Admission to MBioStat or GradDipBioStat or GradCertBioStat) and (BCA801 or STAT8601) and (BCA805 or STAT8604) and (BCA807 or STAT8607)) or ((admission to MAppStat or GradDipAppStat or GradCertAppStat) and (MATH604 or MATH6904) and (STAT818 or STAT6195) and (STAT6110 or STAT810 or STAT8310) and (STAT6114 or STAT814))
Corequisites BCA808 or STAT8609 or (STAT811 or STAT8111 and admission to MAppStat or GradDipAppStat or GradCertAppStat)
Co-badged status
Unit description The aim of this unit is to enable students to use correctly statistical methods of particular relevance to evidence-based health care and to advise clinicians on the application of these methods and interpretation of the results. Unit content: Clinical agreement (kappa statistics, Bland-Altman agreement method, intraclass correlation); statistical process control (special and common causes of variation, quality control charts); meta-analysis estimating treatment effect, assessing heterogeneity, publication bias; application for randomized clinical trials, diagnostic tests and observational studies; advanced topics in clinical trials (cross-over trials, equivalence trials). Because of the multi-institutional nature of the BCA units, there is an early cut-off for enrolment in this unit, which is typically one week before the start of the session. Please contact the program coordinator for details.

## Important Academic Dates

Information about important academic dates including deadlines for withdrawing from units are available at <https://www.mq.edu.au/study/calendar-of-dates>

## Learning Outcomes

On successful completion of this unit, you will be able to:

- ULO1:** Statistical Process Control: Understand the concepts of Continuous Quality Improvement and their usage; Distinguish between Special Causes and Common Causes of variation; Detect Special Causes of variation using a Shewhart control chart;

Detect Common Causes of variation using a CUSUM control chart; Detect Common Causes of variation using a EWMA chart

**ULO2:** Clinical Agreement: Explain the concepts of validity and reliability of measurements; Explain the concepts of agreement and consistency between 2 or more measures and how, for continuous measurements, these relate to simple correlation or regression; Use appropriate graphical and analytical methods to assess agreement between 2 raters using continuous, nominal or ordinal category measurement using Bland-Altman methods and kappa statistics; Use appropriate intra-class correlations for agreement and consistency involving more than 2 raters using continuous scale measurements

**ULO3:** Diagnostic Tests, Systematic Reviews and Meta-Analysis: Calculate measures of performance of a diagnostic test: sensitivity, specificity, and likelihood ratios; Translate the pre-test probability of disease for a particular patient into post-test, predictive values; Plot and interpret a ROC curve; Calculate the diagnostic odds ratio and explain its relationship to the ROC curve; Explain the rationale for doing systematic reviews, rather than narrative reviews; Describe the steps involved in undertaking a systematic review; Conduct a meta-analysis for various study types (including RCTs, observational studies and diagnostic tests) and various outcome variables; Estimate and interpret heterogeneity across studies.

**ULO4:** Clinical Trials: Understand the advantages and disadvantages of using cross-over trials; Prepare appropriate graphical displays of cross-over trial data; Analyse 2x2 cross-over trials with a continuous response using both t-tests and analysis of variance; Produce point estimates and confidence intervals for the parameters of interest in a 2x2 cross-over trial with a continuous response; Understand the underlying assumptions of these analyses and be able to perform appropriate model checks; Analyse 2x2 cross-over trials with binary outcomes; Estimate the sample size required for a 2x2 cross-over trial.; Understand the difference between equivalence and efficacy designs; Appreciate the impact of such designs on analysis principles, e.g. intention-to-treat, especially in the presence of non-compliance.; Calculate the sample size needed in equivalence designs and understand the difference with a similar calculation in a standard efficacy trial; Get some exposure to non-inferiority studies, their role and link with equivalence trials; Calculate the sample size needed in non-inferiority studies; Have an idea on internal validity of equivalence/non-inferiority studies.

## Assessment Tasks

### Coronavirus (COVID-19) Update

Assessment details are no longer provided here as a result of changes due to the Coronavirus (COVID-19) pandemic.

Students should consult [iLearn](#) for revised unit information.

[Find out more about the Coronavirus \(COVID-19\) and potential impacts on staff and students](#)

## Delivery and Resources

### Coronavirus (COVID-19) Update

Any references to on-campus delivery below may no longer be relevant due to COVID-19.

Please check here for updated delivery information: [https://ask.mq.edu.au/account/public/display/unit\\_status](https://ask.mq.edu.au/account/public/display/unit_status)

TBC

## Policies and Procedures

Macquarie University policies and procedures are accessible from [Policy Central \(https://staff.mq.edu.au/work/strategy-planning-and-governance/university-policies-and-procedures/policy-central\)](https://staff.mq.edu.au/work/strategy-planning-and-governance/university-policies-and-procedures/policy-central). Students should be aware of the following policies in particular with regard to Learning and Teaching:

- [Academic Appeals Policy](#)
- [Academic Integrity Policy](#)
- [Academic Progression Policy](#)
- [Assessment Policy](#)
- [Fitness to Practice Procedure](#)
- [Grade Appeal Policy](#)
- [Complaint Management Procedure for Students and Members of the Public](#)
- [Special Consideration Policy](#) (**Note:** *The Special Consideration Policy is effective from 4 December 2017 and replaces the Disruption to Studies Policy.*)

Students seeking more policy resources can visit the [Student Policy Gateway \(https://students.mq.edu.au/support/study/student-policy-gateway\)](https://students.mq.edu.au/support/study/student-policy-gateway). It is your one-stop-shop for the key policies you need to know about throughout your undergraduate student journey.

If you would like to see all the policies relevant to Learning and Teaching visit [Policy Central \(https://staff.mq.edu.au/work/strategy-planning-and-governance/university-policies-and-procedures/p\)](https://staff.mq.edu.au/work/strategy-planning-and-governance/university-policies-and-procedures/p)

[olicy-central](#)).

## Student Code of Conduct

Macquarie University students have a responsibility to be familiar with the Student Code of Conduct: <https://students.mq.edu.au/study/getting-started/student-conduct>

## Results

Results published on platform other than [eStudent](#), (eg. iLearn, Coursera etc.) or released directly by your Unit Convenor, are not confirmed as they are subject to final approval by the University. Once approved, final results will be sent to your student email address and will be made available in [eStudent](#). For more information visit [ask.mq.edu.au](http://ask.mq.edu.au) or if you are a Global MBA student contact [globalmba.support@mq.edu.au](mailto:globalmba.support@mq.edu.au)

## Student Support

Macquarie University provides a range of support services for students. For details, visit <http://students.mq.edu.au/support/>

## Learning Skills

Learning Skills ([mq.edu.au/learningskills](http://mq.edu.au/learningskills)) provides academic writing resources and study strategies to help you improve your marks and take control of your study.

- [Getting help with your assignment](#)
- [Workshops](#)
- [StudyWise](#)
- [Academic Integrity Module](#)

The Library provides online and face to face support to help you find and use relevant information resources.

- [Subject and Research Guides](#)
- [Ask a Librarian](#)

## Student Services and Support

Students with a disability are encouraged to contact the [Disability Service](#) who can provide appropriate help with any issues that arise during their studies.

## Student Enquiries

For all student enquiries, visit Student Connect at [ask.mq.edu.au](http://ask.mq.edu.au)

If you are a Global MBA student contact [globalmba.support@mq.edu.au](mailto:globalmba.support@mq.edu.au)

## IT Help

For help with University computer systems and technology, visit [http://www.mq.edu.au/about\\_us/offices\\_and\\_units/information\\_technology/help/](http://www.mq.edu.au/about_us/offices_and_units/information_technology/help/).

When using the University's IT, you must adhere to the [Acceptable Use of IT Resources Policy](#). The policy applies to all who connect to the MQ network including students.