Standard
L7: Medical Statistician

Institute for Apprenticeships & Technical Education

UOS reference number
ST0892

Trailblazer reference number
TB0478

Title of occupation
Medical Statistician

Trailblazer name
Medical Statistician

Core and options
No

Resubmission
No

Level of occupation
Level 7

Route
Health and science

Typical duration of apprenticeship
30 months

Target date for approval
31 March 2021

Occupational profile

Summary

This occupation is found in a wide range of industries including the Pharmaceutical, Health Care, Medical Device Technology, Biotechnology, Food and Environmental Safety, Regulatory and Academic sectors. The name Medical Statistician and biostatistician are synonymous. For simplicity and alignment to terminology used in numerous universities Medical Statistician is used for this apprenticeship. The broad purpose of the occupation is to provide statistical leadership to a multi-disciplinary team, to ensure research studies are designed, conducted, analysed, interpreted and reported in a way which is statistically valid, such that conclusions are trustworthy and reliable. Research studies are conducted in a wide variety of settings, often designed to test potential new treatments for diseases or to investigate new healthcare interventions. Studies collect data, which is then analysed in order to provide evidence based decisions on whether the new treatment/intervention is advantageous to the patient's condition (e.g. extending life, reducing symptoms or slowing disease onset), whilst ensuring that any unwanted side effects of the treatment are acceptable for the improvement gained. Once enough evidence is gathered, the new treatment/intervention is submitted to a regulatory body for review, with the hope it is approved to be given to patients outside of the research study setting. In their daily work, an employee in this occupation interacts with with regulatory bodies, ethics committee's senior management, study directors, scientists and doctors, data managers, clinical teams, project managers and medical writers to ensure the work they conduct is statistically valid. The role requires good problem solving skills, applying statistical theory to ensure appropriate conduct, and meaningful, reproducible and appropriately interpreted results. The role of a Medical Statistician is primarily office-based spending their time designing studies, monitoring studies, analysing data, writing reports and contributing to team discussions in meetings. The role may also involve some travel to company sites, conferences, scientific and regulatory meetings, workshops and seminars. In an academic setting a Medical Statistician will also have some interaction with students. An employee in this occupation will be responsible for writing/reviewing statistical sections of protocols (including trial design, randomisation schema, study endpoints and sample size), review and input into study collection materials (electronic Case Report Forms, vendor devices), statistical analysis plans (SAPs) (including specifying the format and structure of planned analysis outputs), contributing to grant applications and creating reports for groups such as data monitoring committees. The occupation also involves programming in a statistical package, such as SAS®, R or other appropriate software, creating summaries and graphical representations and performing analyses of data. They ensure statistical model assumptions based on statistical theory have been met and the analyses applied are appropriate. They provide statistical leadership and oversight of a study to a study team as well as managing their own day-to-day workload to ensure project deliverables are met. They interpret the analyses performed, and contribute to study reports and publications such as manuscripts, posters and slide presentations, to ensure results are appropriately disseminated. A Medical Statistician will also be responsible for keeping abreast of current methodological developments in medical research through reading of journals and attendance at conferences, including publishing their own methodology research and sharing knowledge through statistical tutorials for statistics colleagues and also non-statistical specialists.

Typical job titles
['Medical Statistician', 'Biostatistician', 'Statistician']

Duties

Duty	Knowledge	Skills	Behaviours
D1: Lead on the statistical design of medical trials and research projects.	K3, K4, K6, K7, K10, K11	S1, S6, S8, S9, S10, S16	B1, B2, B4, B5
D2: Calculate statistical sample size in medical research to answer the medical research question of interest.	K1, K3, K11	S3	B3, B5
D3: Produce technical writing in medical research	K1, K5, K10	S1, S2, S5, S6, S8	B3, B4
D4: Perform data collection and selection of endpoints/variables in medical research for the therapeutic/disease area of interest.	K1, K4, K10, K12	S1, S2	B1, B2
D5: Select and apply statistical methods applicable for medical research and interpret results	K1, K4, K10, K13	S1, S2, S3, S5	B3
D6: Carry out Data Visualization for reporting of Medical Research:	K1	S2, S4	B3
D7: Critically review medical scientific literature and contribute to ongoing medical research publications	K1	S2, S7, S12, S13, S17	B4
D8: Lead, support and advise on statistical aspects of trials or studies.	K1, K2, K3, K6, K7, K10, K11, K13	S1, S2, S5, S6, S7, S8, S9, S10, S11, S16	B1, B2, B3, B4, B5, B6
D9: Effectively communicate the results from both basic and advanced statistical methods used in medical research	K2, K5	S2, S5, S6, S7, S8, S16, S17	B1, B2, B3, B4, B5
D10: Develop self and others through demonstration of best practice by effective coaching, mentoring, teaching and training.	K6, K8, K9	S6, S7, S8, S14, S15, S16, S17	B1, B2, B4, B6

Knowledge

K1: Statistical knowledge of methods that enable effective analysis of data in research studies.

K2: Project management techniques and strategies (meeting timelines, managing timelines and contingency planning).

K3: Statistical knowledge that enables effective research study design (for example: the drug development process; Study design - parallel group, cross-over, adaptive, placebo controlled, active comparator, open label; Methods allied to different trial objectives – superiority, non-inferiority and equivalence; Randomisation and blinding; Methods for data presentation; Estimands; Missing data strategies; Multiple testing and alpha control methods; Simulation; Sample size and power calculations; Complex innovative designs (CID)).

K4: Strategic approaches to risk and compliance in relation to study design and data collection and interpretation.

K5: Communication and influencing techniques and strategies, both written and oral (including presenting).

K6: Leadership and management techniques and strategies, including coaching and mentoring techniques.

K7: The structure and function of a multidisciplinary team and the role of the Medical Statistician within it, and how to achieve effective partnership working.

K8: Learning and development strategies, to enable personal and professional development, including giving and receiving feedback and critical reflection.

K9: The importance of continuing personal and professional development and the role of critical reflection in maintaining fitness to practice.

K10: Key regulatory authorities and documentation relevant to the study they are working on, for example (International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use Guidelines; European Medicines Evaluation Agency (EMEA); Pharmaceutical and Medical Devices Agency (PMDA); Food and Drug Administration (FDA); The National Institute for Health and Care Excellence (NICE); Medicines and Healthcare products Regulatory Agency (MHRA); Therapeutic area specific guidance; Good Clinical Practice (GCP); Good Laboratory Practice (GLP);Good Manufacturing Practice (GMP)).

K11: Ethics in clinical and non-clinical research.

K12: Methods to safely store and handle data in line with national and international data protection and cyber security regulations.

K13: Health economics methods (including cost benefit analysis, cost effectiveness models).

Skills

S1: Interpret, apply and comply with legislation, statutory frameworks, professional codes of practice and guidance, including quality control.

S2: Select and perform the appropriate statistical technique relevant to the given data set and objective.

S3: Use statistical software (SAS® and R or other appropriate software) to perform the required statistical methods.

S4: Use statistical software (SAS® and R or other appropriate software) to create appropriate graphical and tabular representations of the data to aid interpretation (such as summary tables, individual data listings, histograms, boxplots, scatter plots, line charts, bar charts, frequency tables).

S5: Assess and interpret the results of data analysis and communicate these to peers in written and verbal discussion (such as written medical statistical reports and oral presentations).

S6: Adapt communication technique when communicating statistical concepts to different audiences including people from a non-scientific background.

S7: Critique technical documents affecting projects they are working on, written by other professionals (e.g. medical writers, study directors, project managers, medical consultants).

S8: Provide statistical input into the preparation of technical documents, e.g. study protocols, statistical analysis plans (including specifying the format and structure of planned regulatory required analysis outputs), study reports, regulatory submissions and grant applications.

S9: Identify issues that can affect projects, finding solutions that meet the commercial demands of the business environment.

S10: Lead projects to completion within agreed and defined timescales and project parameters.

S11: Work within limits of personal and professional competence, justifying and taking responsibility for own actions and seeking advice when required.

S12: Search and critically appraise scientific literature, including literature on new and emerging methods and techniques relevant to medical statistics.

S13: Evaluate new statistical methodologies relevant to medical statistics.

S14: Facilitate learning and provide feedback to others as appropriate.

S15: Critically review own practice and identify areas for personal and professional development.

S16: Collaborate with other professionals to deliver mutually agreed outcomes.

S17: Contribute to the wider statistical community (including their own organisation), through sharing knowledge, such as peer review, authorship and co-authorship of papers for publication or presentation at conference.

Behaviours

B1: Be open, honest, compassionate, act with integrity at all times, observe duty of candour and maintain confidentiality.

B2: Be respectful, non-judgemental and engage with people in an inclusive and non-discriminatory manner.

B3: Maintain good character as outlined in professional Code of Conduct and refrain from activities which would bring the profession or organisation into disrepute.

B4: Be adaptable and able to respond professionally to all feedback.

B5: Be prepared to challenge and/or report inappropriate behaviours and practices, using established procedures.

B6: Take a proactive approach to own personal wellbeing, and that of others, reporting concerns as appropriate.

Duty	OTJ days
D1: Lead on the statistical design of medical trials and research projects.	45
D2: Calculate statistical sample size in medical research to answer the medical research question of interest.	30
D3: Produce technical writing in medical research	10
D4: Perform data collection and selection of endpoints/variables in medical research for the therapeutic/disease area of interest.	5
D5: Select and apply statistical methods applicable for medical research and interpret results	2
D6: Carry out Data Visualization for reporting of Medical Research:	5
D7: Critically review medical scientific literature and contribute to ongoing medical research publications	2
D8: Lead, support and advise on statistical aspects of trials or studies.	2
D9: Effectively communicate the results from both basic and advanced statistical methods used in medical research	15
D10: Develop self and others through demonstration of best practice by effective coaching, mentoring, teaching and training.	5

Institute for Apprenticeships & Technical Education

Qualification	Basis for mandation
Medical Statistics Level: 7 (integrated degree) Type: Type 1 Qualification that accredits occupational competence Ofqual regulated: No Awarding bodies • The London School of Hygiene & Tropical Medicine • University of Leeds • University of York • Teesside University • York St John University • University of Reading • University of Lancaster • University of Leicester • University of Sheffield	**Hard sift**

Entry requirements

Typical entry requirements are a 2.2 degree in a numerically based subject.

Professional recognition

No professional body recognition specified

Rationale for no professional recognition

The industry wide professional body, Statisticians in the Pharmaceutical Industry (PSI), does not have any professional recognition. The Royal Statistical Society (RSS) is not specific enough to medical statistics.

Progression routes

No progression routes specified

Progression routes comments

There is a shortage of Medical Statisticians, so people tend to stay in the occupation, but move into more senior roles still working as a Medical Statistician. This could even include being the director of a company, but still leading on medical statistics. People may move sideways into Data Science or Project Management roles as the leadership aspects are transferable. They may also move into other senior leadership roles.

Trailblazer membership details

Chair

Jim Saul (Covance Laboratories)

Facilitator

No facilitator

Employer members

Name	Employer
Adam Smith	Reckitt Benckiser
Alex Godwood	Sosei Heptares
Alison Beaumont	Covance
Amanda Darekar	Pfizer
Ioulietta Mulligan	Worldwide Clinical Trials
Jayne Fountain	Parexel
Jayne Marshall	AstraZeneca
Jennifer Pulley	Roche
Karen Ooms	Quanticate
Kirstie McKay	Covance
Lyn Taylor	Phastar
Martin Johnson	Covance
Mary Elliott-Davey	Amgen
Philippa Hobby	Fera Science
Ricky van Deursen	QIAGEN
Valerie Millar	GlaxoSmithKline

Other members

Name	Organisation
Anna Huber	Teesside University
David Brown	MHRA
Deborah Costain	University of Lancaster
Deborah Stocken	Leeds Uni CTRU
Dimitrios Nicolaou	Teesside University
Jim Taylor	York St John University
Kathy Baisley	LSHTM

Additional information (continued)

Name	Organisation
Muhammad Safwan Akram	Teesside University
Paul Trimmer	Royal Society of Biology
Prof Niall Mackay	University of York
Stephanie Hubbard	University of Leicester
Steven Julious	Sheffield University CTU
Sue Todd	University of Reading