The University Of Sheffield.

Programme Specification

A statement of the knowledge, understanding and skills that underpin a taught programme of study leading to an award from The University of Sheffield

1	**Programme Title**	Advanced Cell & Gene Therapies
2	**Programme Code**	NEUT04 (MSc FT), NEUT05 (PGDip FT), NEUT06 (PGCert FT)
3	**JACS Code**	C460, C431, B300 (HECoS: 101378 (50%) & 100899 (50%)
4	**Level of Study**	Postgraduate
5a	**Final Qualification**	Master of Science (MSc); Postgraduate Diploma (PGDip), Postgraduate Certificate (PGCert)
5b	**QAA FHEQ Level**	7
6a	**Intermediate Qualification(s)**	Postgraduate Diploma (PGDip), Postgraduate Certificate (PGCert)
6b	**QAA FHEQ Level**	7
7	**Teaching Institution** (if not Sheffield)	Not applicable
8	**Faculty**	Health
9	**Department**	School of Medicine and Population Health
10	**Other Departments providing credit bearing modules for the programme**	Not applicable
11	**Mode(s) of Attendance**	Full-time and Part-time
12	**Duration of the Programme**	12 months and 24 months
13	**Accrediting Professional or Statutory Body**	None
14	**Date of production/revision**	November 2023

15. Background to the programme and subject area

Advanced therapies covers highly specialised medical treatments such as cell and gene therapy, which focus on the development of specific and efficient treatments tailored to individual patients. The advanced therapies sector is forecast to grow to a market worth $14-21bn per year and globally by 2025. Currently in the UK, manufacturing of cell and gene-based products suitable for human treatment and commercialisation cannot meet demand, thus there is a bottleneck at the translation stage of moving exciting cell and gene therapies into clinical trials. According to several published reports one of the major limiting factors is the shortage in individuals with expertise and skills in the GMP manufacturing, analytical analysis, quality control and regulatory procedures associated with these technologies. While academic institutions are leading on the discovery front developing cutting edge technologies for advanced therapies, the lack of training in the areas above is not only a general problem for the sector, but it is also a weakness for academic institutions that have invested in developing new tools. We have established a full-time MSc for Advanced Cell & Gene Therapies, at the University of Sheffield thus fulfilling strategic training needs and we are part of the Innovation Hubs for Gene Therapies network (https://www.genetherapyhubs.uk/).

Having established this new MSc course we are being recognised nationally and internationally in the gene and cell therapy field for human application across multiple diseases. We are providing innovative opportunities for training, attracting industrial partnership and developing this area of expertise in the HEI sector. This course is building **capacity and skills** in the latest innovative technologies such as **Advanced Therapies** (genetic and cell therapeutics), one of the major health research priorities identified in the **recent Government Industrial Strategy**.

16. Programme aims

The overall aim of the programme is to train students to become creative analytical thinkers familiar with both basic and clinical aspects of advanced cell & gene therapies, while developing the professional skills needed to work in translational research in the biologics-based treatment sector. The curriculum is designed to allow students to gain:

- An in-depth understanding of the principles of gene and cell therapeutics.
- Develop essential skills and training for each step of clinical development of advanced therapy products: e.g. discovery, vector design, GLP pre-clinical regulatory studies, GMP manufacturing and analytical processes, clinical design and market authorisation.
- Address the shortage of skills and training in this area.
- The ability to critically appraise and analyse scientific literature encompassing both clinical and laboratory-based studies so as to judge and interpret findings.
- Ability to synthesise information from a variety of sources to construct coherent opinions and arguments.
- Critical awareness of the ethical and legal frameworks governing studies with genetically modified organisms, human participants and experimental animals.
- Capability to learn independently and with peers as part of a commitment to lifelong learning and professional development.
- Proficiency in engaging and communicating with diverse communities including lay public, peers and professionals involved in research and clinical practice.
- Ability to evaluate the potential of new and advanced therapies for translation to the clinic.
- An ability to apply analytical and synthetic skills to formulation of new hypotheses.

17. Programme learning outcomes

Knowledge and understanding (MSc K1-6, PGDip K1-5; PGCert K1-4):	
K1	Use detailed knowledge in gene and cell therapeutics and potential applications in monogenic rare diseases.
K2	Apply advanced knowledge in translational path for advanced therapies, including clinical development, GMP manufacturing and regulatory approvals for clinical trials.
K3	Design novel experimental strategies based on current knowledge of genetic factors contributing to human disorders.
K4	Judge the relevance of viral vectors, cell type and animal models to develop treatment for rare disease.
K5	Critique and assess overall landscape of advanced therapies including current challenges.
K6	Design workflows for development of advanced therapies involving academic-industrial partnerships.

Skills and other attributes (MSc S1-8, PGDip S1-7; PGCert S1-7):	
S1	Show ability to retrieve, critically analyse, synthesise and summarise published data from multiple sources, including those which present conflicting data.
S2	Demonstrate independent thought and judgement in relation to critical analysis of scientific literature.
S3	Effectively communicate information using appropriate media (including video) to peers and the general public.
S4	Work both independently and collaboratively in an effective manner to deadlines.
S5	Judge research utilising experimental animal models of disease for adherence to the principles of the 3Rs (reduction, refinement and replacement).
S6	Appraise clinical studies for compliance with national statutory requirements, such as the Human Tissue Act 2004, and local ethical guidelines.
S7	Develop ideas and judgements regarding the development of new gene and cell therapeutics through critical evaluation of appropriate literature, concepts and principles.
S8	Develop competitive practical skills to enable career in industry and academia.

18. Teaching, learning and assessment

Development of the learning outcomes is promoted through the following teaching and learning methods:

The Division of Neuroscience has a proven track record in delivering postgraduate taught programmes which foster an environment with multiple opportunities for individual and group learning. However, the primary responsibility for learning lies with the student, who must be organised and self-motivated to make the most of the programme.

Diverse learning and teaching methods will be used to account for variation in learning styles and maintaining student engagement. Face-to-face learning will be the main mode of delivery. Learning activities will require students to acquire knowledge, both through reading and discussion; investigate topics, both individually and collaboratively; present work using posters and slide presentations; and produce written pieces of work. Students will produce reflective and critical written assignments, posters (both formatively in groups and individually for summative assessment), and presentations to develop communication skills. Scientific ands well as lay writing skills will be developed. Learners will be trained using various platforms: i) F2F lectures with academic and industry experts in advanced therapies; ii) practical sessions in academic and industry labs; iii) tutorials provided by experts in this area; v) opportunity to attend the Annual British Gene & Cell Therapy Conference (available through divisional funding).

Feedback and contact time will be essential for student progression through the programme. Contact time will be provided through lectures, tutorials, discussion round table forums and individual correspondence as and when required and specific tutorials and discussion sessions will allow student to reflect on their learning. MCQs will also be used to provide feedback of knowledge acquisition. Individual responses to incorrect answers can be tailored to provide hints and constructive feedback, rather than just labelling an answer as incorrect. Peer assessment of formative exercises will be used throughout the programme for enhanced feedback.

Opportunities to demonstrate achievement of the learning outcomes are provided through the following assessment methods:

Overall, we use a wide range of assessment methods to measure student knowledge and understanding, including exams, essays, blog articles, poster and oral presentations. The formative assessments are used to encourage group work and/or for students to obtain individual feedback ahead of summative assessments. For example, on NEU61006 (Introduction to Inherited Diseases) students are asked to individually write a paragraph about the genetics of an inherited disease in lay terms prior to writing a blog article as part of their summative assessment (K3, S2, S3)

Summative assessments require students to demonstrate an in-depth knowledge of advanced therapies areas offered by the course: For example, on NEU61008 Principles of Gene Therapy short answer questions in an exam ensure their basic understanding, along two longer questions on the use of cell and gene therapies (K1, K2, K4, S1). In NEU61010, Clinical development in gene & cell therapeutics, the students write a 3000 word critical assessment on regulatory, ethical and safety consideration, challenges and successes of advanced therapies (**K2, K5, S7**). Students will have a choice between gene or cell therapeutics for both assessments.

19. Reference points

The learning outcomes have been developed to reflect the following points of reference:

Subject Benchmark Statements
https://www.qaa.ac.uk/the-quality-code/subject-benchmark-statements/subject-benchmark-statement-biomedical-science-and-biomedical-sciences

Framework for Higher Education Qualifications (2014)
https://www.qaa.ac.uk/docs/qaa/quality-code/qualifications-frameworks.pdf

University Vision and Strategy
https://staff.sheffield.ac.uk/vision

Vision and Strategy Delivery Plan for Education
Strategy Delivery Plan - Education

In addition, the processes of supporting and delivering the part-time and PGCert and PGDip options will build upon the experience gained from the flexible delivery of the MSc in Genomic Medicine. In addition, Prof Janine Kirby (co-lead of the ACGT programme) has been key in the setting up and delivery of all the PGT programmes

previously in the Department of Neuroscience. She led the MSc Translational Neuroscience when it was first set up and then went on to co-lead the MSc Genomic Medicine, obtaining external funding as part of a competitive tender to provide development costs and bursaries for Healthcare professionals to attend the course. She has also been a module lead on these courses as well as others across the School of Medicine and Population Health.

Throughout all the courses, feedback from students and colleagues has informed development of the course.

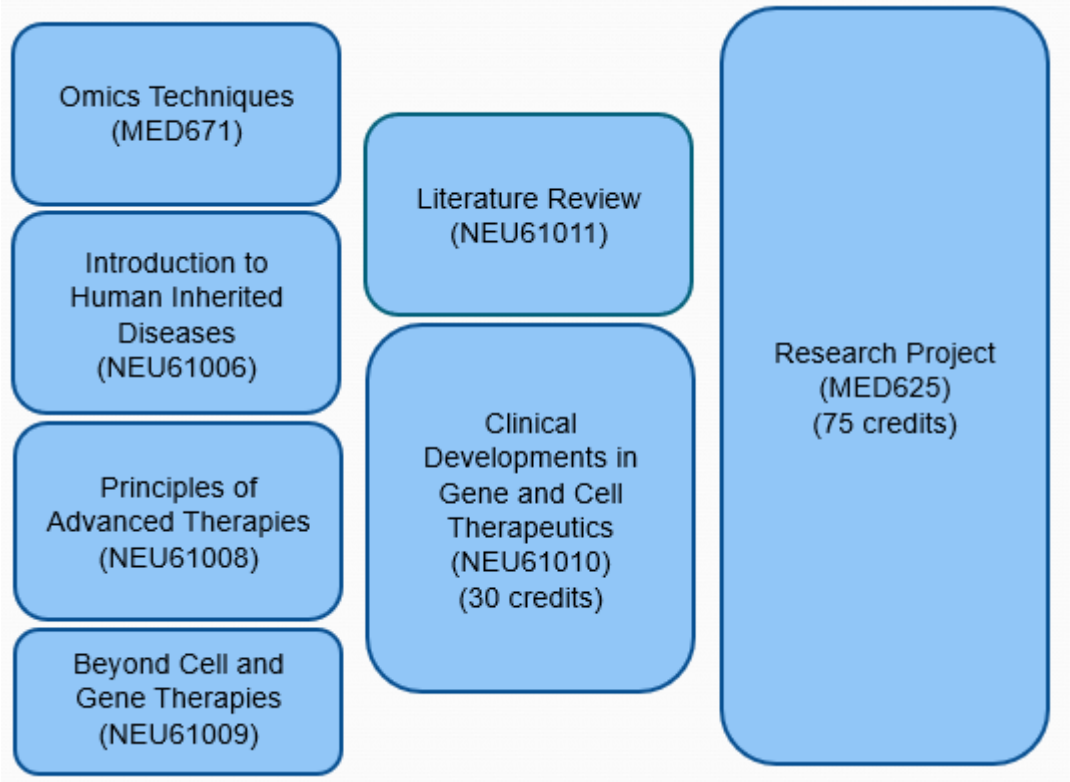
20. Programme structure and regulations

Programme Structure:

Five of the taught modules are 15 credits; 4 are delivered in the Autumn term and then the Literature Review and Clinical Developments modules are delivered in the spring. The research project begins at the end of March and runs to mid-August.

For the PGCert and PGDip qualifications, credits will be obtained from the six taught modules. For the PGDip, a separate module, MED626. Formulating a scientific research proposal, will be undertaken to allow the student to gain 120 credits or they can undertake the MED625 Research Project.

For part-time study, the students will undertake MED671 Omics Techniques, NEU61008 Principles of Advanced Therapies and NEU61011 Literature Review in the first year, and if completing the MSc, will start the research project on a part-time basis. In the second year, students will take NEU61006 Introduction to Human Inherited Diseases, NEU61009 Beyond Cell and Gene Therapies and NEU61010 Clinical Developments in Gene and Cell Therapeutics, before completing their research project. We already have experience of delivering part-time projects from when we taught the part-time MSc Genomic Medicine.



Detailed information about the structure of programmes, regulations concerning assessment and progression and descriptions of individual modules are published in the University Calendar available on-line at http://www.sheffield.ac.uk/calendar/.

21. Student development over the course of study

The programme is designed so that students progressively achieve more advanced levels of skills, learning and practice. The course will be recruiting from a wide background of knowledge and skills, e.g. biology, chemistry, engineering, pharmacy, medical. In phase 1 (first 6 months), students will be introduced to the genetic factors associated with inherited diseases, how this facilitates disease modelling, and provides insight into how gene and cell therapies can be adopted as treatment options for these disorders. They will also learn about the principles of gene and cell therapies. The course will also offer a comprehensive road map on the required steps to take an advanced therapy project from discovery to clinical trials then marketing authorisation. Students will undertake formative writing and presentation assessments during the content block prior to summative assessment in the assessment block, with a major emphasis on developing critical skills alongside scientific and lay communication skills.

In the second phase, students will undertake an MSc project. They will have several options: i) a lab-based research project; ii) a project related to GMP manufacturing, potentially located at a GMP facility such as the GTIMC in Sheffield; iii) a project related to other Advanced Therapy Medicinal Products, such as in the regulatory process; iv) a project with a clinical team undertaking clinical trials with advanced therapy products. Project allocation may take into account student's ability to travel to the GTIMC and their previous knowledge. It is envisaged that students who currently work in the industry would be able to develop a project based at their current work. All external projects would be reviewed by the ACGT Education team to ensure they were compliant and a UoS co-supervisor would be appointed. The student will complete a 6,000 word dissertation in the style of a journal paper focused on gene or cell therapeutic development which is supported by one-to-one supervision.

Students may also have opportunities to expand their potential during their research projects through exposure to ongoing industry partnerships between researchers and their external collaborators e.g. biotech or pharma companies working in advanced therapeutics.

22. Criteria for admission to the programme

The course will attract candidates from a wide range of disciplines. To secure a place in the PG Cert, PG Dip or MSc, they will be expected to have a good (upper second-class honours or better) degree or an equivalent qualification in a relevant Science or Clinical subject: e.g. Neuroscience, Biomedical Science, Psychology, Biomedical Engineering, Medicine or biological subject as well as Pharmacy, Science, Engineering, Law or Nursing subject.

Candidates for whom English is not a first language and who do not hold a GCSE Grade C (or equivalent) in English, will be expected to have an IELTS (International English Language Testing System) qualification with a mean of 6.5 (with a minimum of 6.0 in each component).

The programme will retain PGCert and PGDip as exit qualifications.

23. Additional information

Information on the wealth and breadth of Neuroscience research at the University of Sheffield, in particular the neurodegeneration research at SITraN, can be found by browsing the following websites:

http://sitran.org/

https://www.sheffield.ac.uk/neuroscience

http://sheffieldbrc.nihr.ac.uk/

https://www.sheffieldclinicalresearch.org/about/our-directorates/neuroscience/

This specification represents a concise statement about the main features of the programme and should be considered alongside other sources of information provided by the teaching department(s) and the University. In addition to programme specific information, further information about studying at The University of Sheffield can be accessed via our Student Services web site at http://www.shef.ac.uk/ssid.