

Metrology on a cellular scale for regenerative medicine

The need for the project

With an increasingly ageing population there will be times when we will all require some form of healthcare support in order to manage disease and maintain our quality of life. However, the challenge for healthcare providers and governments is to manage these potentially spiralling health costs. Significant savings could be made through tissue regeneration; growing new cells to replace damaged or diseased tissue, thereby removing the need for long-term drug treatment and the possibility of adverse side effects.

This project aimed to support regenerative medicine by developing robust procedures for cell growth measurement and characterisation, and by defining cost effective metrics for assessing the consistency of products containing living cells.

Technical achievements

Support for regulation:

Techniques such as CARS (Coherent Anti-stokes Raman Spectroscopy) and MALDI (Matrix-Assisted Laser Desorption/Ionization Imaging) spectrometry have been developed. These can be used to characterise the behaviour of cells in regenerative medicine products.

Support for healthcare:

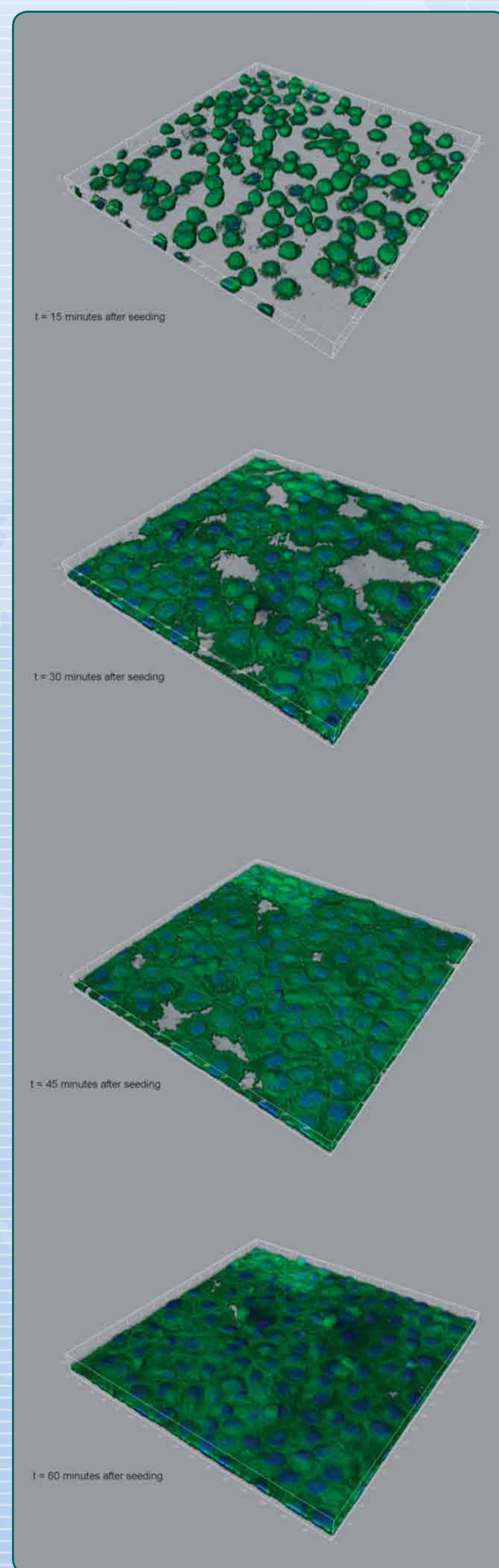
This project has developed specialised methods to understand the measurement uncertainty associated with diagnostic evaluation of cells in clinical samples.

Support for innovation:

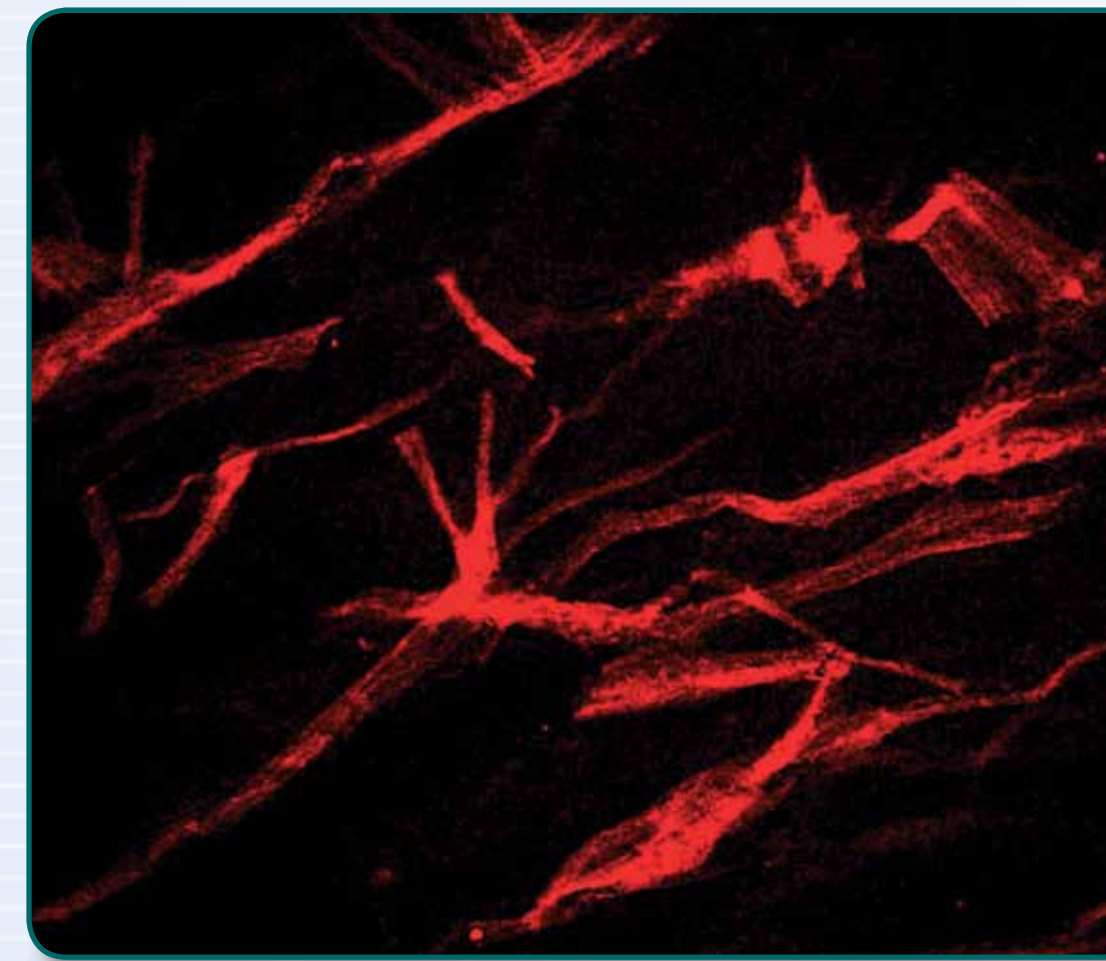
The measurement science developed in this project is being used to support work in EU specialised centres, such as through dissemination activities organised by the Fraunhofer Institute (e.g. The World Congress on Regenerative Medicine), and by direct links with technology innovation centres.

Support for the social acceptance of regenerative medicine products:

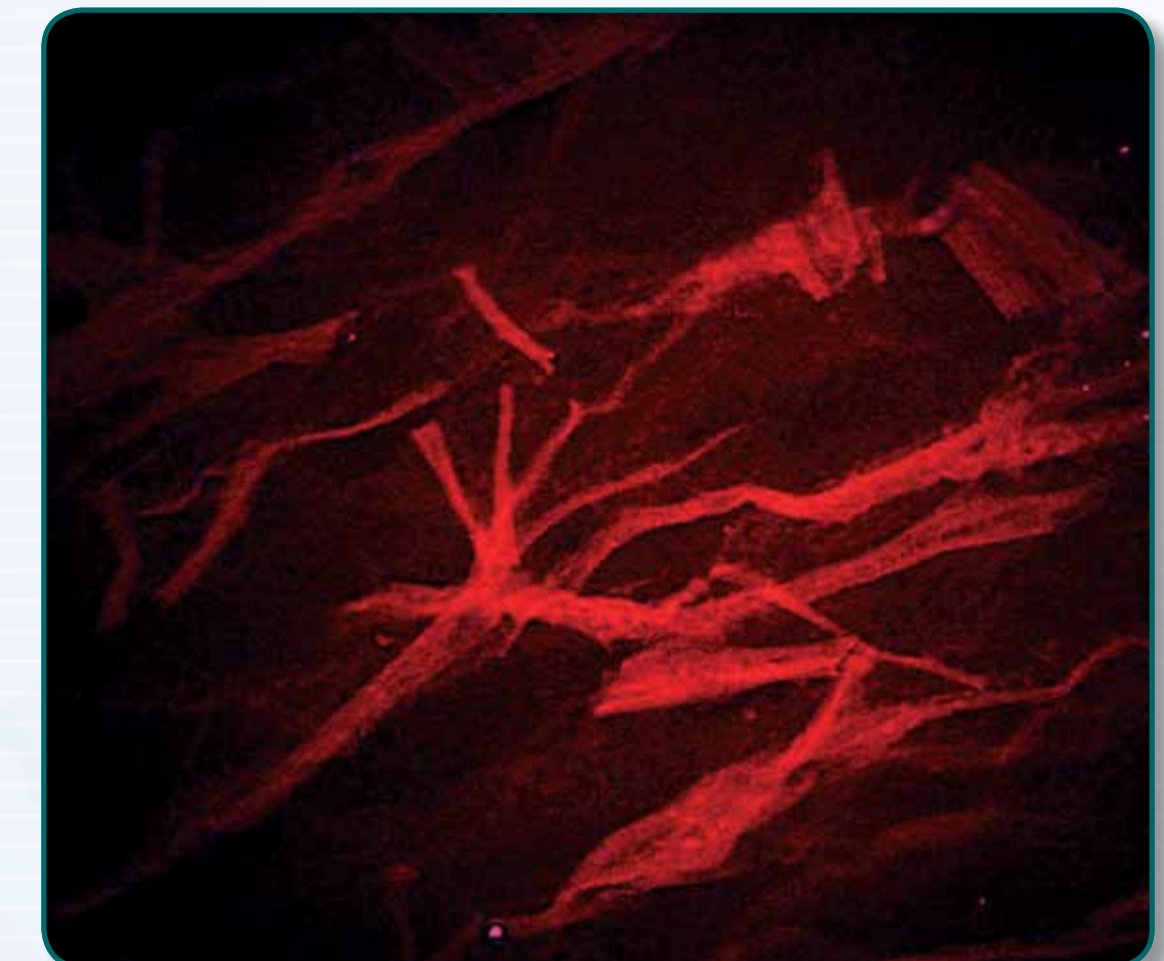
This project developed measurement techniques to ensure products are safe and well characterised when used in humans.



Quantifying the time dependent changes in cell shape that occur as they attach to surfaces can be exploited to enhance the biocompatibility of surfaces.



CARS imaging of fibroblasts grown in fibrin gel at day 7.



CARS imaging of fibroblasts grown in fibrin gel at day 21-note the collagen produced.

Meeting European legislation

Developed measurement technologies and methodologies that enable European companies to meet the requirements for cell characterisation, as defined in the Advanced Therapy Medicinal Product Directive 2009/120/EC. They have also input into standardisation bodies; ISO Technical Committee 150 - *Implants for surgery*, ASTM International Committee F04 - *Medical & Surgical Materials & Devices* and BSI Committee RGM/1 - *Regenerative Medicine*.

Centre of Excellence for regenerative medicine

Enabled project partners to act as a virtual 'Centre of Excellence' for regenerative medicine and the characterisation of cell containing products. The project has also provided stakeholders with access to cutting edge measurement technology such as Two-Photon Excitation Fluorescence Microscopy, CARS, MALDI and Desorption Electrospray Ionization (DESI) Mass-Spectrometry.

Support to the medical community

Supported medical companies in the development of new biomaterial surfaces that cells can easily adhere to, using traditional textile technologies.

Helped cell therapy companies to develop cell characterisation techniques that do not rely on animal testing.

Enabled spectroscopic techniques (developed for studying cell culture biomarker molecules) to be applied in the detection of counterfeit medicines.

Allowed companies using fluorescent biomarkers to obtain reliable results and to have more confidence in their analysis.