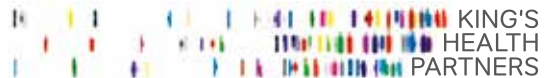


King's Clinical Research Facility



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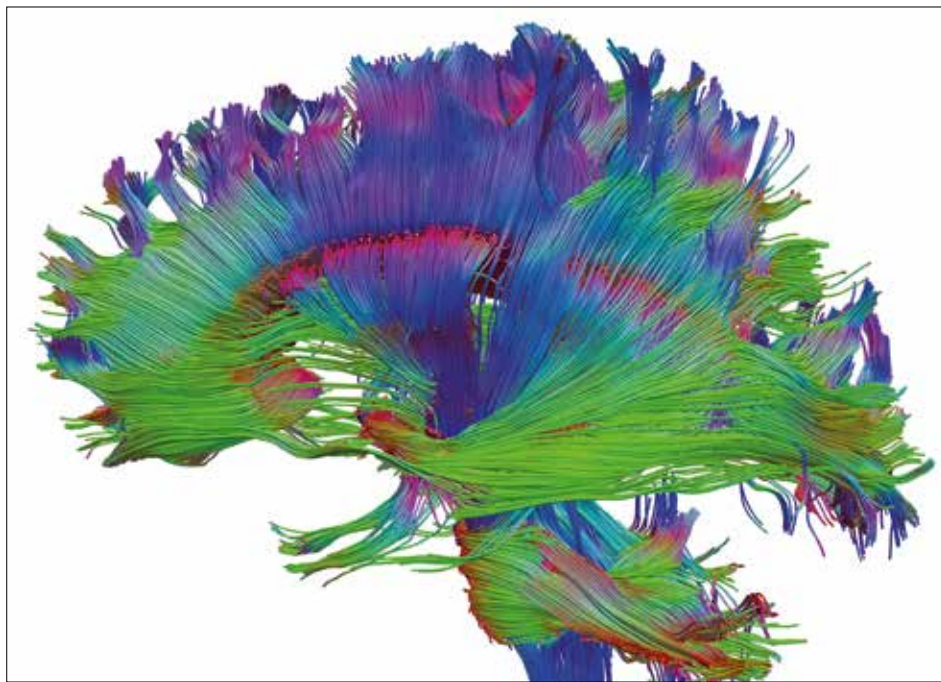
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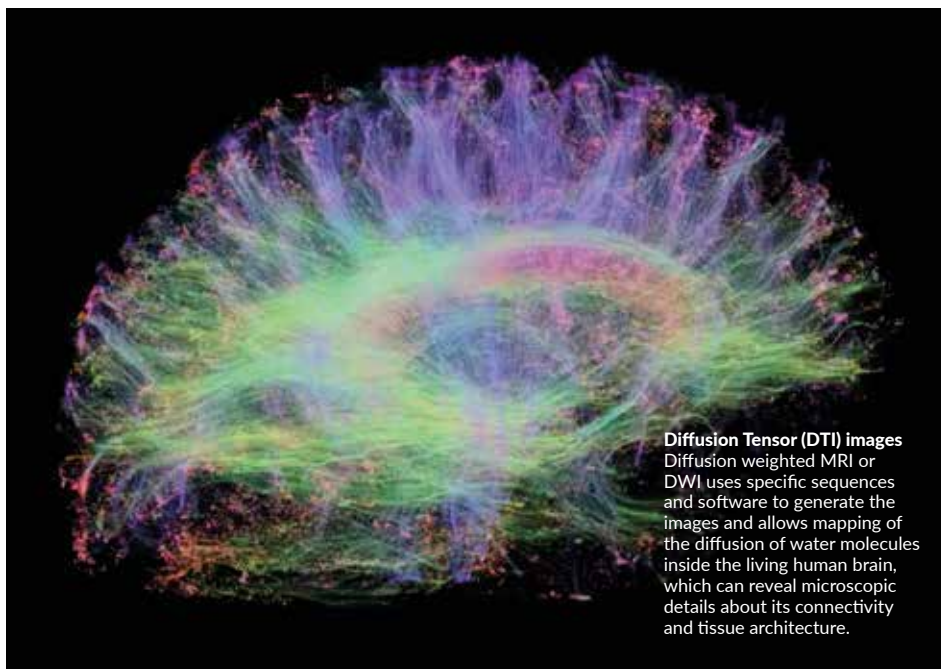
Welcome

The **NIHR/Wellcome King's Clinical Research Facility (CRF)** was formally opened by Dame Sally Davies, Chief Medical Officer in May 2014 and comprises two main research facilities within *King's College Hospital*, spanning three floors and a standalone unit, the *Clinical Trials Facility*. The CRF was partly funded with a capital award from Wellcome Trust and additional awards from its Academic Health Science Partners, *King's College London*, *South London* and *the Maudsley, Guy's and St Thomas'* and *King's College Hospital NHS Foundation Trust*. Additional capital contributions were received from various donors, a list of which can be seen at our front Reception.

Each area has been designed and built to complement the other in terms of ability to offer a unique and neutral space to carry out clinical trials in a dedicated research setting. We are keen to facilitate the work of established investigators, and encourage, support and assist new investigators in an environment that allows academic, clinical and industrial partners to collaborate in a research setting with a full clinical backup service. We can accommodate all types of trials ranging from day and overnight studies to longer term stays. Our focus is particularly for experimental, translational, and early phase trials. Later phase studies can be brought to the Clinical Research Facility with appropriate arrangements.



FLAVIO DELLAQUA



Diffusion Tensor (DTI) images

Diffusion weighted MRI or DWI uses specific sequences and software to generate the images and allows mapping of the diffusion of water molecules inside the living human brain, which can reveal microscopic details about its connectivity and tissue architecture.

FLAVIO DELLAQUA

NIHR/WELLCOME TRUST KING'S CLINICAL RESEARCH FACILITY

CTF CLINICAL TRIALS FACILITY

Administrative Centre

Ward Beds inc 3 x side/
isolation rooms

Infusion chairs

Examination rooms

Renal Dialysis facilities

Quiet lounge

Sleep rooms

Dedicated parking
spaces

Calibrated Equipment

Sample processing
room with centrifuge,
fridge, -20°C and -80°C
freezer

IT Network to King's
College London, King's
College Hospital, South
London & Maudsley

EMF EXPERIMENTAL MEDICINE FACILITY (NEW UNIT)

Ground Floor

MRI: 3T functional MRI
(fMRI)

2 x HDU beds

4 x ward beds (directly
supervised through
nursing station)

IT data room

Secure Cryostore

1st Floor

Main reception

4 x Interview rooms
with video recording
and observation facility

2 x Clinical rooms

8 x Infusion/
phlebotomy chairs

2 x EEG recording
rooms

Virtual Reality suite

Physiotherapy suite

Recreation area

CTU CELL THERAPY UNIT (NEW UNIT - 2ND FLOOR)

GMP facility with three process suites

+ Grade B suite with
closed processing in 1
Grade A isolator: **Cell
isolation**

+ Grade D suite with
closed processing in 3
Grade A isolators: **Cell
Therapy**

+ Grade D suite with
closed processing in 2
Grade A isolators: **Cell
& Gene Therapy**

Controlled non-
classified area
comprising cryostore
(sited on Ground floor),
cold pack, prep and
waste treatment

Common area & sample
handling (outside
CTU): QC lab, changing
rooms, meeting room,
write up & staff
refreshment room



1 The Experimental Medicine Facility



The **Experimental Medicine Facility (EMF)** is housed over two floors of the CRF. Entry to both floors of the EMF is via the main hospital corridors of King's College Hospital. The CRF has a purpose built, step-free, security controlled entrance.

“Thank you for all your help with my VR body image research. I felt very welcome and looked after! Wishing you all the best.”

Researcher

First floor

The main entry and reception area is situated on the first floor of the EMF. On this floor there are easily-accessible study subject changing facilities, four interview rooms with video recording facilities, two clinical rooms each with an examination couch, and an open plan area with six reclining chairs for sampling and monitoring study subjects. Additionally, there are two state of the art electroencephalography (EEG) purpose built rooms for both prone and sitting recording and use with computer stimuli. The EEG is designed to provide capacity for



Above (1, 4) example of the VR bus, exterior and interior, **(2)** VRS and **(3)** the VR cafe

close monitoring. It is electronically and acoustically shielded, providing a uniquely optimal environment for the study of subjects undergoing EEG monitoring; and allowing highest-quality multi-modal data collection of EEG, electromyography, electrocardiography and respiration.

There is a purpose built virtual reality suite (VRS) on this floor, which provides a sophisticated integrated system comprising computer hardware, graphic systems and the capacity for feedback, allowing participants to

control the virtual environment through a multitude of flexible sensors. This provides the ideal methodology for real-time assessment of thoughts, mood and symptoms as they occur. These are used for psychological interventional studies. More information can be found at kcl.ac.uk/iop/about/campus/loP-virtual-tour.aspx

The remainder of the floor provides appropriate indoor and external balcony space for relaxation, recreation and refreshment for study subjects.

Appropriate accommodation for nursing staff and medical staff involved in on-going studies is available on this floor.

Ground Floor

The ground floor of the EMF includes a two-bedded intensive care facility for the study of critically ill patients following stroke, trauma, and brain injury, or who are ventilated. Additionally there is a four-bedded area for experimental medicine studies, with capacity to monitor closely aspects of study subject physiology, such as cardiovascular and respiratory parameters. This area is directly supervised by a nursing station. A neuroimaging suite is situated at the rear of the ground floor. It comprises a new 3T functional GE MRI (fMRI) scanner, a control room, an image analysis room, clinical preparation rooms and a research office.

The coexistence of MRI with the aforementioned EEG, VRS, behavioural assessment and biological sampling facilities, under the same roof, provides a unique environment for multimodal imaging and integrated collection of large data sets. Moreover, the imaging facility is perfectly suited for the assessment of less ambulatory patients, especially when serial assessments are needed during the disease course: for example, after stroke, surgery or brain injury. There is world-class academic

support offered by the Neuroimaging theme of the SLaM Mental Health-BRC, with expertise in brain image acquisition and analysis techniques. The ground floor can be adapted as required to accommodate paediatric and adolescent studies.

In addition, the ground floor of the EMF houses the IT data room for the CRF, a recycling waste storage area, easily accessible to the main King's College Hospital corridor, and a dewar storage facility for the delivery and storage of liquid nitrogen for the Cell Therapy Unit. The unit houses a bed lift to access all floors.





2 Facility for commercial trials



The ground floor of the **Clinical Trials Facility (CTF)**, has been designed in conjunction with current users and industrial collaborators, providing a state of the art facility for commercially sponsored clinical trials. The CTF divides into two major areas; a bedded/chair facility, with one isolation (quiet) room bed, and a suite of 11 fully reclining chairs.

“Thanks to all the wonderful staff at CRF, and best wishes to everyone in the Cold Hands, Warm Heart! Your #1 patient”
Volunteer

Clinical Areas

Both areas are open plan with easy access to private individual consulting rooms where study subjects can be interviewed and examined appropriately and confidentially. Throughout the CTF there are nursing stations with easy visibility to the clinical areas. The area is equipped with an emergency call system to ensure that patients can be located wherever they are in the unit. The CTF is designed for both day patient usage, overnight stays and if required, longer term stays. To accommodate this capacity there



is a range of amenities including appropriate shower room facilities and dedicated lounge and entertainment facilities. In addition there is a fully equipped kitchen to ensure that meals can be both provided from the hospital or prepared on site if required. A small garden area provides an outdoor facility for study subjects who are not able to leave the CRF complex. To accommodate studies of varying duration in the CTF, there are appropriate facilities for nursing and medical staff involved in the supervision and care of study subjects. This includes computer terminals and clinical equipment. The CRF maintains documentation on all its

equipment in terms of calibration/ maintenance and has remote temperature monitoring for frozen and refrigerated samples.

There is a fully equipped sample processing room within the CTF for the management of biological fluids, the separation of blood and refrigeration for short term storage of relevant materials, until samples can be transferred to the appropriate laboratories for measurement or longer term storage.



In order to be competitive in clinical trials activity there has been a need to develop regulatory and contractual expertise with the partner organisations. This has been achieved by establishing the Kings Health Partners - Clinical Trials Office, (KHP-CTO). The KHP-CTO has an office within the CTF.

The CTF is designed for both day patient usage, overnight stays and if required, longer term stays.



3 The Cell Therapy Unit



The second floor of the CRF houses the **Cell Therapy Unit (CTU)**. In terms of manufacturing capacity, this the largest facility of its kind currently built in either academia or industry in Europe at time of writing, with capacity to produce more than six final products simultaneously and with potential for production of around 1,000 therapies annually.

“The CRF is a shining example of a high quality research environment. Pharmaceutical companies are very happy to have Kings CRF as a site”
Clinician

King’s CRF Cell Therapy Unit

This is a complex and sophisticated GMP Unit built to the exacting standards required to meet the licensing requirements of the MHRA and other regulatory bodies for the manufacture of human cell and gene-based therapies. The CTU is divided into three main production areas:

1. One Grade B suite for cell isolation, consisting of three clean rooms where three processes can be worked on independently;
2. One Grade D suite for cell therapy closed processing, consisting of three production rooms and one

“As a first time user I worried that I would be an outsider but all the staff have been friendly and accommodating”
Clinician

support room where more than three processes can be undertaken simultaneously;

3. and one Grade D suites for cell gene therapy with an accompanying support room, where two processes can be carried out simultaneously.

Ancillary areas for cold pack, liquid nitrogen storage, preparation, consumables stores and waste disposal support the clean rooms. The environment is compliant with current legislation for GMP facilities and suitable for the processes which will be carried out, which enforces biological containment. This includes the design for movement of personnel, materials, products and waste throughout, appropriate equipping of the facility, ensuring that the room layouts are fit for purpose and provide all that is necessary to safely and cleanly carry out the wide portfolio procedures required



by the user groups. A sophisticated environmental monitoring system supports the CTU infrastructure.

The Common Area and the Samples-Handling Laboratory

Outside of the CTU facilities, but situated on the second floor, is a common area for the CRF comprising a quality control laboratory with capacity for dealing with clinical samples, a meeting room, a write-up room for investigators involved in on-going studies, offices for permanent CRF staff, an area for staff relaxation and refreshment, and minimal store room capacity.



This is a complex and sophisticated GMP Unit built to the exacting standards required to meet the licensing requirements of the MHRA and other regulatory bodies for the manufacture of human cell and gene-based therapies.

Notes

The NIHR CRF is supported by a team of expert research nurses, technicians, a quality and data support team and is directed by Peter Goadsby, Professor of Neurology. The Facility is operationally led by Elka Gienza the CRF Manager and she is supported by the lead nurse, Noah Yogo. We provide full nursing support for early phase clinical trials and academic studies and can undertake many research activities such as PK/PD sampling, lumbar punctures, IV infusions, glucose tolerance tests and lung function assessment's. Other activities include supporting microneurography, Transcranial Magnetic Stimulation (TMS), EEG and MRI scanning and we have space to undertake unrestricted 6 minute walk tests. We have particular expertise in supporting mental health and neurological trials.



**All information contained
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