Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

ACCREDITATION CERTIFICATE FOR

PHASE I CLINICAL TRIALS UNITS

Section 1: Administrative Data

Section 1.1 Unit Details

Company name	Hammersmith Medicines Research
Full address	Cumberland Avenue
	London
Post Code	NW10 7EW
Contact name	Malcolm Boyce
Telephone no	020 8961 4130
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Section 2: ACCREDITATION OF UNIT

Section 2.1 Accreditation Assessment

Based on the information provided in the application form, plus associated accreditation/re-accreditation inspection(s) by the MHRA GCP Inspectorate the above unit has been assessed as being in general compliance with the requirements (as defined in Appendix 1) of the phase I accreditation scheme.

Section 3: KEY PERSONNEL

Section 3.1 Responsible Personnel for Medical & Clinical Support

The above classification is based on the Unit having appropriate numbers of staff with adequate training and experience to handle medical emergencies. The following staff have been nominated as key personnel:

Name	Job Title
Malcolm Boyce	Executive Chairman, Medical Director and FIH PI
Steve Warrington	Chief Medical Adviser and FIH PI

Dawn Jeffries	**Team Leader (nurse)**
Dawn Sherman	**Staff Training Manager**
Kirsten Heukelbach	**Head of Pharmacy Production**
Frans van den Berg	**Research Physician**
Sarah Boulton	**Ward Manager**
Kate Darwin	**Director of Scientific Services**
Robyn Johnson	**Night Team Leader (nurse)**
Wendy Calvert	**Team Leader (nurse)**
Adeep Puri	**Senior Research Physician and PI**
Amanda Peter	**Director of Pharmacy**

Section 4: CONDITIONS OF ACCREDITATION

The above accreditation is based on the Unit continuing to maintain satisfactory standards for avoiding harm to trial subjects and for handling medical emergencies should they arise.

Significant changes to the content of the application on which the assessment /inspection was based must be notified to the MHRA GCP Inspectorate. Significant changes are those that affect the key elements upon which the accreditation was based for example:

- Relocation of the unit, or addition/change to facilities (e.g. extension of existing unit, the permanent use of facilities at another location).
- Significant change to procedures that impact on key aspects of the accreditation scheme (e.g. changes to procedures relating to medical emergencies, subject recruitment, resourcing and staffing, minimum staffing requirements, risk assessment etc.)
- Changes in key personnel - titles used for key personnel will differ between organisations and units will need to review the requirements in the accreditation scheme and determine which personnel are key to attaining and maintaining those requirements. However, in general, these will be the medical doctors, including the Medical Director (or the medical doctor who has overall responsibility for medical aspects), any PIs authorised for FIH trials (or the person responsible for assessing the PI for a clinical trial), Senior Nurses, Clinic Manager (i.e. the person who has overall responsibility for the day to day running of the clinic and the clinic equipment, e.g. emergency trolley) and the Pharmacist or individual responsible for the emergency drugs.
- Significant contractual changes in agreements with local hospitals.

ISSUED BY:	**DATE ISSUED:**
Andrew Gray, Group Manager, GLP/GCP/PV MHRA GCP Inspectorate	5/11/15 **EXPIRY DATE:** *3 years from date of issue*