

**ACCREDITATION CERTIFICATE FOR
PHASE I CLINICAL TRIALS UNITS**

Section 1: Administrative Data

Section 1.1 Unit Details

Company name	Hammersmith Medicines Research (Ward A only)
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 inspection dated 5th January 2009 the above Unit has been assessed as being in general compliance with the requirements of the accreditation scheme for a **Standard and Supplementary** Unit based on the following classification:

Standard – Accredited to carry out all Phase I trials other than FIH trials with risk factors that would require EAG review

Supplementary – Accredited to carry out trials with compounds at all levels of risk including those that require review of risk factors by EAG*



* Examples of trials where expert advice may be sought include First in Human trials with novel compounds :

- where the mode of action involves a target that is connected to multiple signalling pathways (target with pleiotropic effects) e.g. leading to various physiological effects or targets that are ubiquitously expressed
- acting (directly or indirectly) via a cascade system where there may be an amplification effect which might not be sufficiently controlled by a physiological feedback mechanism
- acting (directly or indirectly) via the immune system with a target or mechanism of action which is novel or currently not well characterised.
- where there is novelty in the structure of the active substance eg a new type of engineered structural format such as those with enhanced receptor interaction as compared to the parent compound
- where the level of expression and biological function of the target receptor may differ between healthy individuals and patients with the relevant disease
- where there is insufficient available knowledge of the structure, tissue distribution, cell specificity, disease specificity, regulation, level of expression and biological function of the human target, including down-stream effects
- acting via a possible or likely species specific mechanism or where animal data are unlikely to be predictive of activity in humans

Section 3: KEY PERSONNEL

Section 3.1 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	PI and Managing and Clinical Director
Steve Warrington	PI and Medical Director
Dawn Jeffries	Team Leader (nurse)
Dawn Sherman	Staff Training Manager
Kirsten Heukelbach	Head of Pharmacy Production
Brian Kay	Head of Pharmacy QC
Robert Adams	Research Physician



Renee de Waal	Research Physician
Min Hui Ho	Research Physician
Frans van den Berg	Research Physician
Benjamin van Hecke	Research Physician
Yuet Lewis	Projects Director
Sarah Boulton	Ward Manager
Kate Dunn	Director of Clinical Science
Robyn Johnson	Night Team Leader (nurse)
Lee Meng Choong	Senior Research Nurse and Phase II Trainer
Wendy Calvert	Team Leader (nurse)

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 basis upon which the accreditation was based for example:

- Relocation of the Unit, or addition of facilities (e.g. extension of existing unit, the permanent use of facilities at another location)
- Changes in key personnel
- Significant contractual changes in agreements with local hospitals.

The accreditation of the new site is based on the inspection of Ward A only, and will be reviewed following a full systems inspection within 6 months

ISSUED BY:



Rebecca Harrison, Group Manager GCP. GPvP,
GLP

DATE ISSUED:

11 Feb 2009.

EXPIRY DATE: 30th September 2009

