ACCREDITATION CERTIFICATE FOR

PHASE I CLINICAL TRIALS UNITS

Section 1: Administrative Data

Section 1.1 Unit Details

Company name	Richmond Pharmacology Ltd
Full address	Croydon University Hospital
	530 London Road
	Croydon
	Surrey
Post code	CR7 7YE
Contact name	Dr Ulrike Lorch
Telephone no	020 8664 5200
Fax	020 8664 5201
Mobile	
Email	u.lorch@richmondpharmacology.com

Section 2: ACCREDITATION OF UNIT

Section 2.1 Accreditation Assessment

Based on the information provided in the application dated /inspection date 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 e.g. 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
Dr Ulrike Lorch	Medical Director and PI (FIH)
Dr Jorg Taubel	Chief Executive Officer and PI (FIH)
Dr Radivoj Arezina	Research Director

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 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.

ISSUED BY:	**DATE ISSUED:**
M Stanbrook Rebecca Stanbrook, Group Manager GCP, GLP, GPvP MHRA GCP Inspectorate	1st March 2013 **EXPIRY DATE:** *2 years from date of issue*