

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 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:



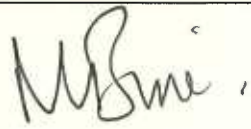
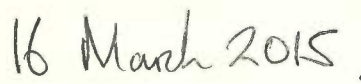
Name	Job Title
Dr Ulrike Lorch	Medical Director and PI (FIH)
Dr Jorg Taubel	Chief Executive Officer and PI (FIH)
Dr Radivoj Arezina	Research Director

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/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.

<p>ISSUED BY:</p> <div style="text-align: center; font-size: 2em; margin: 10px 0;">  </div> <p><i>Mark Birse, Group Manager, Inspectorate, I,E&S division, MHRA</i></p>	<p>DATE ISSUED:</p> <div style="text-align: center; font-size: 1.5em; margin: 10px 0;">  </div> <p>EXPIRY DATE: <i>2 years from date of issue</i></p>
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