NIHR Royal Liverpool and Broadgreen Clinical Research Facility

Heather Rogers Research Governance Manager
RLBUHT

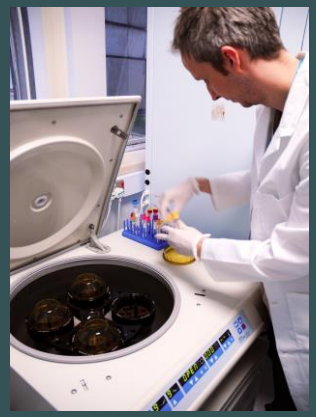
Why????

- Phase 1 accreditation is voluntary
- MHRA accreditation costs around £22k

Phase 1 Unit history

- 2009 – 6 bedded unit with 3 full time staff
- 2010 – GCP sponsor inspection
- 2012 – 6 single rooms added
- Strategic alliance with COVANCE
- Strong Academic links
- Applied in January for MHRA Phase 1 accreditation 2012

Facilities

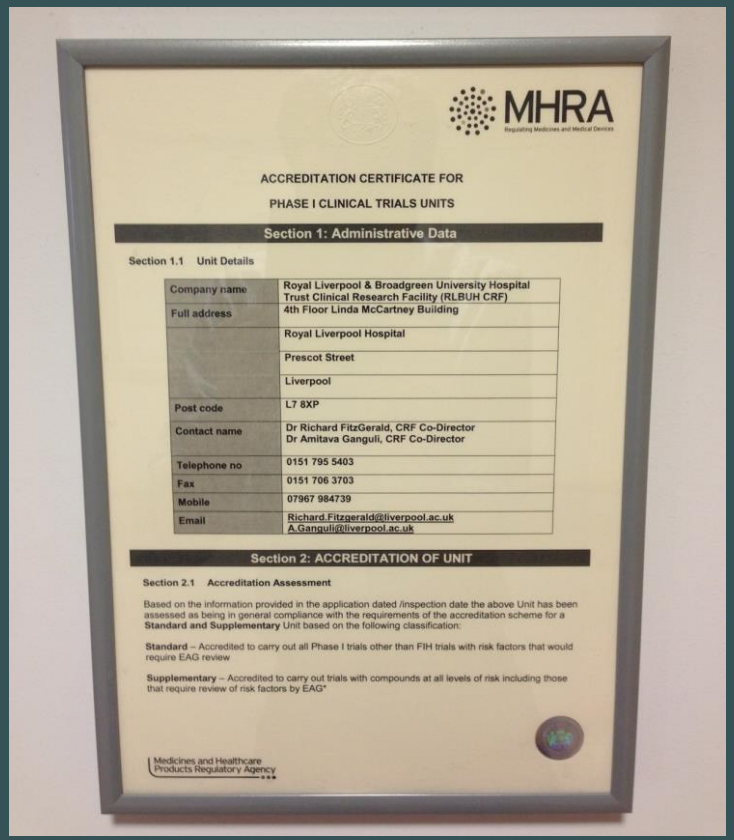


12 bedded unit (24/7)
Sample processing lab
Biorepository (-20° & -80°C freezers)
Treatment Room
Telemetry for 4 beds
Participant facilities
In-house lab safety testing
Clinical Trials Pharmacy
Archiving

Abilities

Bronchoalveolar lavage
Muscle and skin biopsies
^{14}C dosing

Aspiration



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ACCREDITATION CERTIFICATE FOR

PHASE I CLINICAL TRIALS UNITS

Section 1: Administrative Data

Section 1.1 Unit Details

Company name	Royal Liverpool & Broadgreen University Hospital Trust Clinical Research Facility (RLBUH CRF)
Full address	4th Floor Linda McCartney Building
	Royal Liverpool Hospital
	Prescot Street
	Liverpool
Post code	L7 8XP
Contact name	Dr Richard FitzGerald, CRF Co-Director Dr Amitava Ganguli, CRF Co-Director
Telephone no	0151 795 5403
Fax	0151 706 3703
Mobile	07967 984739
Email	Richard.Fitzgerald@liverpool.ac.uk A.Ganguli@liverpool.ac.uk

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*

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List of Accredited Phase I Units

Name of Unit	Location	Type of Accreditation	Date of Accreditation
Bio-Kinetic Europe Ltd	Belfast	Standard and Supplementary	19 July 2011
Celerion GB Ltd.	Lisburn Road, Belfast	Standard and Supplementary	10 May 2013
Covance Clinical Research Unit	Leeds	Standard and Supplementary	24 May 2013
Edinburgh Clinical Research Facility (WTCRF & RIECRF)	Edinburgh	Standard and Supplementary	12 July 2013
GSK Clinical Unit Cambridge	Addenbrooke's Hospital, Cambridge	Standard and Supplementary	15 July 2011
Hammersmith Medicines Research	Cumberland Avenue, London	Standard and Supplementary	04 November 2011
Medicines Evaluation Unit	Southmoor Road, Manchester	Standard and Supplementary	05 July 2013
Parexel Clinical Pharmacology Unit	Northwick Park Hospital, London	Standard and Supplementary	12 April 2013
Quintiles Drug Research Unit at Guy's Hospital	Newcomen St, London	Standard and Supplementary	10 August 2012
Quotient Clinical	Ruddington, Nottingham	Standard and Supplementary	10 May 2013
Richmond Pharmacology	Mayday Hospital, Croydon and St Georges Hospital	Standard and Supplementary	01 March 2013
Simbec Research Limited	Merthyr Tydfil	Standard and Supplementary	25 September 2012
Surrey Clinical Research Centre	Guildford	Standard and Supplementary	01 August 2012
Royal Liverpool & Broadgreen University Hospital Trust Clinical Research Facility (RLBUH CRF)	4th Floor, Linda McCartney Building, Royal Liverpool Hospital, Prescot Street, Liverpool	Standard and Supplementary	10 May 2013
Respiratory Clinical Trials Ltd: Nephrology and Urology Clinical Trials and Queen Anne Medical Centre (incorporating Heart Lung Centre)	Queen Anne Street, London	Standard and Supplementary	22 March 2013

Last updated: 18th July 2013

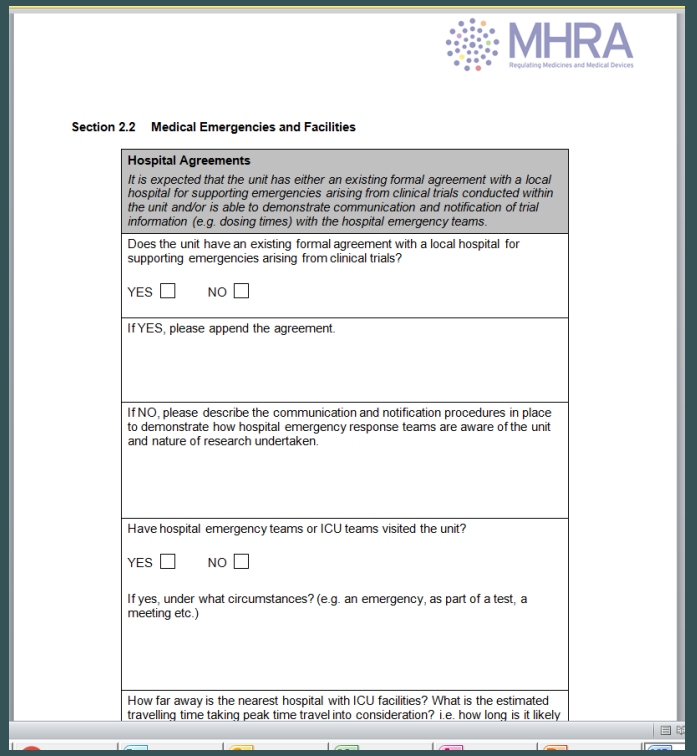
Medicines and Healthcare Products Regulatory Agency

Inspection prep

- Bench marked with Edinburgh

Dossier

- Unit details and inspection history
- Facilities and procedures
- Requirements for EAG trials
- Key personnel
- declaration



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Section 2.2 Medical Emergencies and Facilities

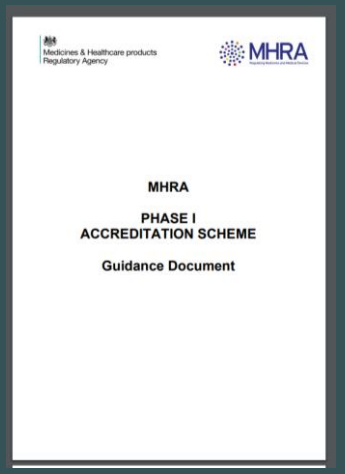
Hospital Agreements *It is expected that the unit has either an existing formal agreement with a local hospital for supporting emergencies arising from clinical trials conducted within the unit and/or is able to demonstrate communication and notification of trial information (e.g. dosing times) with the hospital emergency teams.*
Does the unit have an existing formal agreement with a local hospital for supporting emergencies arising from clinical trials? YES ☐ NO ☐
If YES, please append the agreement.
If NO, please describe the communication and notification procedures in place to demonstrate how hospital emergency response teams are aware of the unit and nature of research undertaken.
Have hospital emergency teams or ICU teams visited the unit? YES ☐ NO ☐ If yes, under what circumstances? (e.g. an emergency, as part of a test, a meeting etc.)
How far away is the nearest hospital with ICU facilities? What is the estimated travelling time taking peak time travel into consideration? i.e. how long is it likely

Clinical trial spread sheet for dossier

	W	X	Y	Z	AA	AB	AC	AD	AE	AF	AG	AH	
	Sponsor Delegated Tasks	Is this trial in relation to a RMP?	Is the trial contained in a current/planned regulatory MA submission?	MA Submission Reference Number (if applicable)	TMF	Name of eTMF system (if electronic)	Location of TMF (if paper)	CRF/diaries systems	IRT	PV database used	Primary or Secondary Laboratory Endpoints	Lab stopping criteria	Type moni
	This column should be completed by all organisations. Please specify what activities are delegated. As sponsor this should be those activties delegated to a CRO or vendor. For CROs and vendors this should list the activties you are responsible for. A more comprehensive list of the CROs and their delegated activities should be completed using the worksheet 'delegated tasks'	If you are the sponsor please detail if the trial is in relation to a Risk Management Plan (RMP) associated with a marketing authorisation condition.	If you are the sponsor, please confirm if the trial report is pivotal (e.g. is used or to be used in a marketing authorisation application to the EMA or the national regulatory authority of a Member State) or key decision making trial.	If yes, please give details (e.g. application reference number), otherwise leave blank	Please confirm what type of TMF is being used (e.g. paper, electronic or hybrid) where appropriate give the system name	Enter the name and version of any electronic system, if one is used (as a whole or hybrid TMF).	Please confirm where the TMF is located if the TMF is wholly or partly paper (e.g. trial, country and investigator site leve), especially if not located in the UK	If the trial is using any electronic CRFs or diaries (e.g. eCRFs, ePROs etc.) please enter name and version of system(s). Leave blank if no electronic systems are used.	If the trial is using any interactive response technology, such as interactive voice or web based systems (e.g. IRT/IWRS etc.) please	If you are the sponsor or CRO with this delegated task please confirm what type of pharmacovigilance system is in place (e.g. paper or electronic). If electronic please enter the name and version of the system used. Otherwise	If you are the sponsor or CRO with this delegated task please confirm if there are any primary or secondary laboratory endpoints (e.g. PK, PD or BE). If yes highlight the laboratory responsible for analysis the samples in the delegated task worksheet. Otherwise please leave blank.	If you are the sponsor or CRO with this delegated task please confirm if there are any laboratory stopping criteria. If yes please highlight the laboratory responsible for analysis the samples in the delegated task worksheet. Otherwise please leave blank.	If you are the sponsor or CRO with this delegated task, please confirm what type of monitoring is

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
udraCT lumber	Protocol / Trial Reference Number	Title	Risk Adaption Category	Name Chief / Principal Investigator at your site	Number of Subjects Recruited at your site	Trial Status (UK)	Trial Start Date	Trial End Date (if completed)	Number of SAEs at your site	Number of SUSARs at your site	Therapeutic area	External Sponsor			
[illegible]	Local trial protocol number or reference (e.g. for non-commercial organisations your reference number is acceptable.	Full trial title to be provided.	A, B or C if applicable (see http://www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con111784.pdf). leave blank if not known.			Live, Completed, Terminated Early (please give reason	Start date (e.g. first subject first visit) at your site	End date (e.g. last subject last visit) at your site	Number of SAEs at your site only	Number of SUSARs at your site only	Function or division (e.g. Oncology, Diabetes etc..	Name of Sponsor or Co-sponsors			

Specific to phase 1



- Anaphylaxis training & emergency scenarios
- Emergency alarm testing
- Dose escalation policy
- Minimum qualifications for PI's and prove they were on site at dosing
- Subject recruitment
  - Over volunteering
  - Photo ID
  - GP questionnaires

MHRA Phase I Accreditation

- Inspected in March 2012 & November 2012

- 1st hospital in England and Wales to hold this accreditation

Lessons learnt

- Joint learning about NHS v commercial unit
- Phase 1 inspections are different
  - GCP
  - Phase 1 accreditation requirements
- Phase 1 Contracts and oversight are different
- Continuity planning – FIH ready medics
- Visiting researchers

Post inspection work

- Report
- Quality management meetings
- CAPA trackers
- Issues of repeat findings
- Don’t forget “observations” and “recommendations”

- Reporting of changes outside inspection

MHRA Phase I Accreditation

- Inspected in March 2012 & November 2012
- Received Accreditation Certificate in May 2013
- Received Reaccreditation in Jun 2015 – lasts for 3 years
- Re-inspected Mar 2018 – Reaccreditation for 2 years

- 1st NHS hospital in England and Wales to hold this accreditation

New Facilities – Opening ?2020

- 26 Bed - 24/7
- Larger Sample Processing Laboratory and Storage
- Staff growth to support
- Single Bedrooms or 4 bed bays for high risk trials
- Improved Patient Facilities
- GMO capabilities

Risk v. Benefit

- Trust reputation
- Financial

- Maintaining and improving
- General improvement
- Continued investment
- Collaborations and benchmarking