Appendix 4

BRITISH ASSOCIATION OF DERMATOLOGISTS BIOLOGICS REGISTER

RESEARCH GOVERNANCE: STAKEHOLDER ACCOUNTABILITIES AND RESPONSIBILITIES

Introduction

The British Association of Dermatologists Register (BADBIR) is a non-interventional observational study to collect information concerning patients treated under normal conditions with licensed medicines (the "Project"). The Project and its intellectual property are owned by the British Association of Dermatologists Biologics Register Limited ("BAD") and it operates as an academic independent programme free from influence by the pharmaceutical industry.

It has been agreed that BAD will be the project owner and main funder of the register and the role of sponsor, as defined in the Department of Health's Research Governance Framework ("RGF"), will be fulfilled by the University of Manchester "UoM").

Governance Structure and Accountabilities

The main contract for the Project is between BAD and UoM. UoM has been contracted by BAD and is accountable to BAD for the overall conduct of the BADBIR project. To fulfill the requirements of the RGF, Professor Chris Griffiths is the designated Chief Investigator.

Independent review and oversight of the progress of the Project is provided by the BADBIR Steering Committee which acts as a sub-committee to the BAD Executive. In addition a small data monitoring and ethics committee has full access to the data and provides advice on matters relating to patient safety and statistics to the investigators and the steering committee.

Patients are only admitted to the Register after decisions about their condition and future treatment have been made by the care professionals who prescribe and manage their treatment. Both patients and their care professionals provide data to the BADBIR.

To protect the academic independence of the research team and the review committees an independence " fence" has been established between the research & review teams and the pharmaceutical companies providing the funding. Dialogue with the pharmaceutical companies is closely managed through the BAD Clinical Project Manager. Separate contracts exist with each pharmaceutical company who provide finance to the BAD which is restricted to the purpose of funding the register. In return each company may request and receive copies of data in relation to patients treated with their company's product and those patients who are in the control cohort.

For regulatory purposes the BADBIR operates as an independent academic research project and is not subject to medicines regulatory law and guidelines. Data and information on adverse event episodes are forwarded by the research team to the pharmaceutical companies to enable them to comply with European law governing the timely reporting of adverse events from individual case safety reports and the preparation of periodic safety update reports to the regulatory authorities.

In line with the RGF and after consultation with the UoM the key responsibilities of each role are described below.

Role Responsibilities

The allocation of responsibilities in the project are described in the following table

Item	Responsibility	UoM	CI	PI	BAD	PHARMACO
General	Provide an appropriate process of independent expert review that ensures and maintains that the research is worthwhile, of high scientific quality and good value for money.				X	
	Ensure and demonstrate compliance with the requirements of the RGF	X	X	X	X	X
	Maintain a project master file with all key Project documents including study materials, past and present staff CV and training records and copies of all publications.		X			
	Monitor the overall conduct and execution of the Project to ensure compliance with the contract between BAD and the UoM. Such monitoring will include routine audit by the UoM. BAD may also request to audit the study.	X			X	
	Ensure there is an adequate assessment of project risks in place to secure and protect paper records, IT systems and business continuity of the project over the full life cycle.	X	X	X		

Item	Responsibility	UoM	CI	PI	BAD	PHARMACO
1. Study Preparation	a) Ensure that insurance or indemnity arrangements are in place to cover liabilities arising from the management and design of the study. For its part the UoM is able to compensate without proof of negligence or incurring obligation.	X				
	Ensure insurance or indemnity arrangements are in place to cover the conduct of University staff or BAD staff on University premises –UOM	X				
	Ensure that insurance or indemnity arrangements are in place to cover the conduct of BAD staff or UoM staff on BAD premises				X	
	b) Secure and administer funding for the Study	X			X	
	c) Ensure that the appropriate contracts and agreements are in place for the Study	X			X	
2. Applications and Registration	a) Ensure that the Protocol has undergone independent scientific and statistical review and is compliant with the relevant regulations / guidelines		X			
	b) Prepare participant information sheet and consent form and other relevant documents prior to ethics submission		X			
	c) Prepare and submit ethics application		X			
	d) Obtain NHS permission			X		
	e) Obtain local REC approval			X		

Item	Responsibility	UoM	CI	PI	BAD	PHARMACO
3. Protocol amendments	a) Prepare and submit proposed substantial amendments of the Protocol to the BADBIR steering committee and where agreed to the relevant ethics committees.		X			
	b) Secure approval for changes to the protocol with the pharmaceutical companies				X	
	c) Ensure all investigators are aware of dates of approval and implementation of all such amendments		X			

Item	Responsibility	UoM	CI	PI	BAD	PHARMACO
4. Study Conduct	a) Responsibility to ensure that investigators conduct the study in accordance with Good Clinical Practice, the RGF and the laws and statutes, and any local requirements as may be specified by the host institution	X	X	X		
	b) Ensure that the arc EU research team members are appropriately qualified to undertake the conduct of the study and that they have current substantive or honorary employment contracts in place, where required.	X	X			
	c) Ensure that no participant is recruited to the study until satisfied that all relevant regulatory permissions and approvals have been obtained		X	X		
	d) Put and keep in place arrangements to allow all investigators to conduct the study in accordance with the protocol		X	X		
	e) Ensure that the study is conducted in accordance with the agreed research protocol *except where necessary to eliminate an immediate hazard(s)* - These circumstances must be reported to the CI who will be responsible for reporting within the sponsor organisation, the [BAD DMEC], and to the research ethics committee		X	X		

Item	Responsibility	UoM	CI	PI	BAD	PHARMACO
4. Study Conduct	f) Personal responsibility for the design, management and reporting of the study		X			
	g) Responsibility for monitoring the study in accordance with the arrangements outlined in the submission to the Sponsor		X			
	h) Ensure that the rights of individual participants are protected		X	X		
	i) Ensure that patients receive appropriate medical care whilst participating in the study			X		
	j) Inform appropriate health or social care professionals if their patient is a participant in the study in accordance with the RGF			X		
	k) Maintain and archive study documentation at the arc EU	X	X			
	l) Maintain and archive study documentation at the local NHS site			X		
	m) Ensure that all data and documentation are available for the purposes of monitoring, inspection or audit.	X	X	X	X	
	n) Ensure appropriate consent has been provided by each participant before data are transferred to the arc EU and a copy of this consent is kept with the patient medical record.			X		
	o) Ensure adequate facilities, resources and support are available to conduct the study at the arc EU	X				

	p) Ensure adequate facilities, resources and support are available to conduct the study at the local NHS site			X		

Item	Responsibility	UoM	CI	PI	BAD	PHARMACO
	q) Responsibility to report and assist with investigations into any alleged research misconduct undertaken by or on behalf of the Sponsor	X	X	X	X	X
5. Adverse events	a) Maintain detailed records of all serious adverse events as specified in the protocol		X			
	b) Report serious adverse events as agreed in the protocol and to legal requirements and in accordance with University policy		X	X		
	c) Ensure that 24 hour SAE reports, monthly reconciliation reports, and 6-monthly reports are generated and submitted in a timely fashion to the relevant pharmaceutical companies as specified in the Pharmacovigilance Standard Operating Procedure.		X			
	d) Ensure that all investigators are, at all times, in possession of the current relevant safety information for the study		X		X	
	e) Ensure that important and/or urgent safety matters are communicated to the DMEC to receive independent advice and that such matters are notified to the UoM as employer and sponsor		X			
	f) Provide six monthly reports on the incidence of serious adverse events to the DMEC		X			
	g) Provide quarterly reports on recruitment and 6 monthly lists of deaths and certain SAEs to the BADBIR steering committee		X			

Item	Responsibility	UoM	CI	PI	BAD	PHARMACO
	h) Ensure that end of study reports are generated and submitted to the relevant pharmaceutical companies, BAD DMEC and BADBIR steering committee (where agreed) within the required timeframes		X			
6. Data Management	a) Design of report forms and database		X			
	b) Ensure that all reasonable efforts are used to ensure that the data collected, recorded in the database and reported are accurate, complete and identifiable at source; and that record keeping and data transfer procedures adhere to the Data Protection Act 1998 and the UoM data protection policy		X	X		
7. Publication	a) Maintain a rolling publications plan and secure input and support for it with the BADBIR steering committee				X	
	b) All publications to be reviewed by the appropriate interested parties as per the publications process outlined in the contractual agreements between the parties		X		X	X
	c) Produce reports for each biologic product on completion of data collection for that cohort		X		X	
8. End of Study and Data Archiving	a) Responsibility to notify all stakeholders of the end of the study (including if terminated early)	X			X	
	b) Ensure that all study records are archived appropriately on conclusion of the study and retained for 10 years.	X	X		X	

University = University of Manchester (UoM)
Chief Investigator = Chief Investigator as Listed on Main Study MREC Application
Principal Investigator = Designated principal investigator at each local NHS site
BAD = British Association of Dermatologists
PHARMACO= Pharmaceutical Company for each biologic agent being studied