RIVER Registry –RIVaroxaban Evaluation in Real life setting

Title of Registry	Prospective, multicentre, international Registry of male and female patients newly diagnosed with Atrial Fibrillation and treated with Rivaroxaban
Registry Number	**TRI08890**
Protocol Version Number	**Protocol version 1.0** **9th February 2015**
Sponsor	The Thrombosis Research Institute, London
Type of Study	Registry
Investigational Medicinal Product	None
Chief Coordinating Investigator	Professor the Lord Ajay K Kakkar
Registry Objectives	To assess the rate of stroke and systemic embolisation in Registry participants To assess patient outcomes with specific reference to: • The incidence of bleeding complications • Therapy persistence (including discontinuation, interruption and changes of therapy regimen)

Registry Endpoints	• Cerebrovascular events defined as stroke, including:
	  ○ Primary ischaemic stroke
	  ○ Primary intracerebral haemorrhage
	  ○ Secondary haemorrhagic ischaemic stroke
	• Transient ischaemic attacks (TIAs)
	• Systemic embolisation
	• Pulmonary embolisation
	• Acute coronary syndrome; including unstable angina, STEMI and non-STEMI
	• Bleeding events including:
	  ○ Frequency
	  ○ Location
	  ○ Severity (classified as major, clinically relevant non-major and minor)
	• Therapy persistence (rate of discontinuation, duration of time on therapy, reasons for discontinuation)
	• Duration and cause of treatment interruption or suspension

	• Analysis of events listed with regard to hospitalisation and outcomes • Any other hospital visits (inpatient, outpatient, and emergency) • Mortality • Major adverse cardiac events For patients subsequently treated with VKA additionally: • Frequency and timing of monitoring required in maintaining therapeutic anticoagulation • INR recordings in relation to therapeutic range • Location of INR monitoring and medical consultations due to INR testing • Use of bridging anticoagulation necessitated by vitamin-K antagonist interruption • Outcomes in relation to INR fluctuation For patients treated with anticoagulation therapy: • Patient treatment satisfaction will be assessed using the ACTS questionnaire (where validated languages are available).
Registry Design	This is a non-interventional, multicentre, prospective Registry.
Number of patients	5,000 patients with newly diagnosed non-valvular AF of any cause with at least one Investigator-determined risk factor for stroke will be enrolled.
Patients	Males and females aged 18 years and over
Inclusion Criteria	1. Written informed consent 2. Age 18 years and over 3. New diagnosis of non-valvular atrial fibrillation (diagnosed within the last 6 weeks) with at least one additional investigator-determined risk factor for stroke 4. Initial treatment with Rivaroxaban following AF diagnosis
Exclusion Criteria	1. Patients for whom long-term follow up is not envisaged or possible within enrolling hospital or with associated primary care physician 2. Patients with transient AF secondary to a reversible cause 3. Patients participating in an interventional study that dictates treatments, visit frequency or diagnostic procedures 4. Not treated with Rivaroxaban as first treatment
Registry Conduct	Suitable patients will have been diagnosed in the following settings:

	▪ Hospital (Neurology, Cardiology, Geriatrics, Internal medicine) ▪ Stroke Unit ▪ GP, family practice and community ▪ Anticoagulation clinic/system ▪ Emergency Department • The determination of additional risk factor(s) for stroke will be left to the clinical judgement of the investigator. • All patients satisfying the inclusion/exclusion criteria will be considered for enrolment. A log of all patients invited to participate in the Registry will be kept for each site. Potential patients will be invited to take part in the Registry and their medical history checked to exclude any patients not suitable. • All patients will be provided with the patient information sheet. • Written informed consent will be obtained according to local requirements before any Registry-related procedures (i.e. transfer of data from the medical records to the CRFs). • Data will be collected at baseline, 4, 8, 12, 16, 20, and 24 months. These time points will be used as markers for collection of all information from the interim period since the last data milestone. The aim of data collection will be to accurately capture all planned and unplanned visits, treatment interruptions and events.
Registry Duration	It is anticipated that the total registry duration will be approximately 3.5 years allowing approx. 18 months for recruitment and 2 year follow-up of the last patient enrolled.