

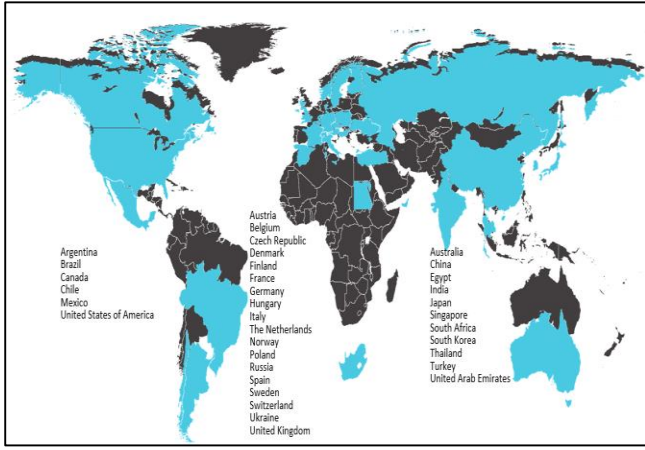


# Registry News

***Congratulation – Over 53,000 patients enrolled!***

## Thrombosis Research Institute Update

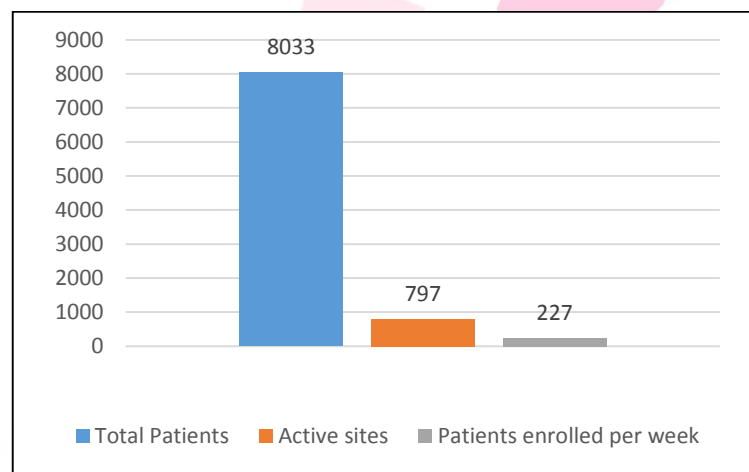
### Participating Countries - Garfield AF



## Recruitment Update – Cohort 5

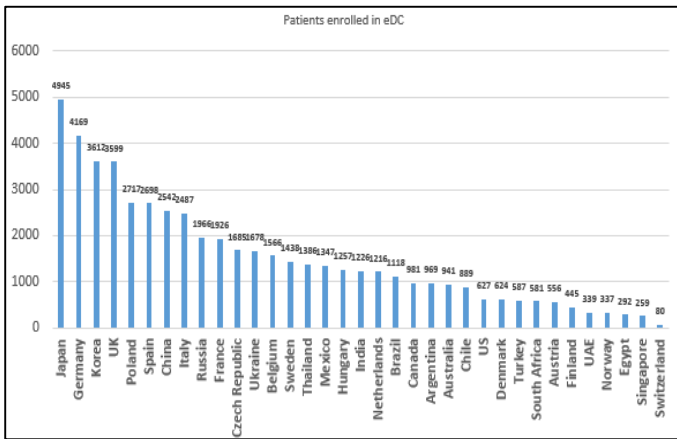
To date (15/04/2016) 8,033 patients have been enrolled into Cohort 5. The target for Cohort 5 is 12,000 patients to be enrolled until end of July 2016.

TRI encourages all the sites to actively enrol in order to ensure that the global recruitment target of 57,000 patients and 12,000 patients for Cohort 5 is met by the end of the recruitment period on 31<sup>st</sup> July 2016. The graph below summaries the number of actively recruiting sites and the number of patients enrolled in total and per week in cohort 5.



## Global Recruitment Update

As of 15 April 2016, globally 53,085 patients have been successfully recruited against the target of 57,000 patients ensuring Garfield-AF remains the largest, active, prospective atrial fibrillation registry in the world. Garfield-AF aims at clarifying atrial fibrillation treatments and outcomes for patients, clinicians and healthcare workers around the globe.



## Garfield-AF Publications

- TRI team worked closely with Steering Committee and Publication Committee to submit 5 abstracts to European Society of Cardiology in February 2016
- All our investigators are highly encouraged to participate in the publication plan for the registry. Please refer to the TRI-Garfield website\* for the publication ideas that have already been submitted and are under consideration.
- New idea (International or National level), please contact the National Co-coordinating Investigator with your idea and a joint publication can be proposed by the NCI of your country to the Garfield-AF Steering Committee.

\*You can request for the login details for TRI Garfield-AF website by sending an email on [Garfield@tri-london.ac.uk](mailto:Garfield@tri-london.ac.uk)

## Operational Priorities 2016-2017

- Recruitment – End of enrollment by 31<sup>st</sup> July 2016
- Data Lock
- Data Cleaning
- Data Collection
- Entering Patients into Follow-up Extension
- Implementation of ACTS
- Garfield-AF - Audit

### Data Lock

All the sites must lock all the data on an ongoing basis by using the 4 digit Principal Investigator PIN. This confirms that the data entered is complete, accurate and can be used for analysis.

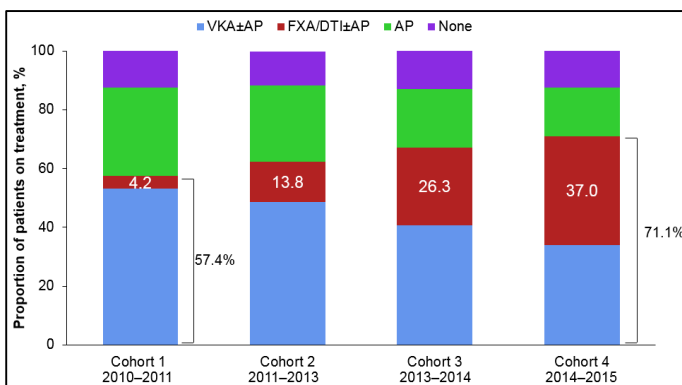
The table below summaries the percentage of data locked to date (1/04/2016).

Milestone	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5
Baseline	100%	100%	100%	99%	90.85%
Month 12	99.07%	99.3%	98.0%	67.0%	
Month 24	98.99%	99.0%	68.0%		

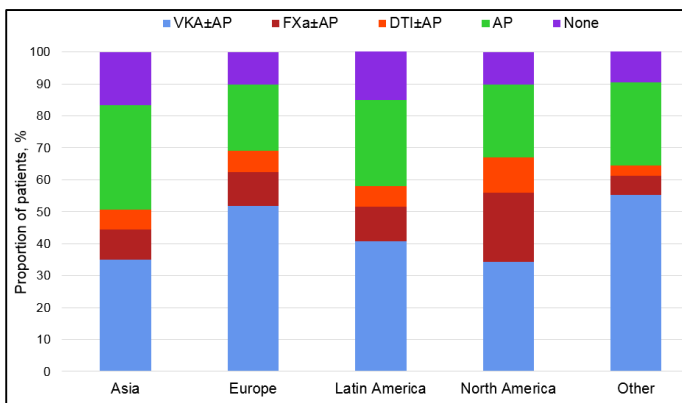
Please note that 99% of the data needs to be locked by the sites for TRI to perform the data analysis.

## Garfield-AF Data Showcase

Evolution in baseline treatment for patients enrolled in sequential cohorts of GARFIELD-AF



Anti-thrombotic treatment in patients with AF by region



### Data Cleaning

To ensure data completeness and accuracy, the data management team at TRI has prepared a detailed site level workbook containing information on all the data discrepancies at the site. This document will be shared with your site shortly by your site manager, alongside clear instructions and training regarding respective data entry. We encourage sites to complete the discrepancies in Dendrite and help ensure that Garfield AF is as accurate as possible.

### Data Collection

As a part of the latest protocol amendment, Garfield AF now captures information regarding named drugs and doses for certain anti-coagulant drugs on the 'Treatment at diagnosis' or 'Treatment Change/interruption' page. We encourage all our sites to provide TRI with the required information for the applicable records.

## Entering Patients into Follow-up extension

- We would also like to remind all our investigators to enter patients into the follow-up extension (extending the patient follow-up beyond 24 months)
- This long term follow-up data will help TRI analyses outcomes in patients and also the change in treatment practices over time. Thus TRI encourages all sites and patients to participate in the extended follow-up for the registry
- During the follow-up extension – only yearly follow-up is required and the data entry for all the events has been significantly reduced

## Completion of ACTS questionnaire – Only for specific countries

*Tips for implementation of the ACTS questionnaires:*

- Record the patient ID on the ACTS Questionnaires.
- **Do not record patient names.**
- At the top of each Questionnaire in the booklet, write the date on which the time-points will fall:  
- Month 4, Month 12 and Month 24 post commencement of AC treatment.
- Instruct each patient to complete and return the questionnaires on schedule.
- Instruct the patients to complete the questionnaire(s) thinking about how he/she is feeling in the past 4 weeks while on treatment.
- Remember to inform each patient that the Questionnaire is double sided, and both sides should be completed.

To order additional questionnaires at the site please contact your local site manager or email directly to TRI at [garfield@tri-london.ac.uk](mailto:garfield@tri-london.ac.uk).

## Garfield-AF Audit

According to the protocol, Source Data Verification will be undertaken in a minimum of 20% of all cases. To meet the protocol requirement. Over 200 sites and more than 2,000 patients have been monitored to date in 2 phases. For Phase 2, concordance of 94.0% was recorded between the source data and the CRF value, this value further increased to 95.6% in Phase 3 of monitoring. TRI would like to thank all the sites for diligence while entering the patient data.

TRI is planning to implement the next phase of on-site monitoring. During this phase selected sites will be visited for the Source Data Verification against the CRF data. If your site is selected, you will be contacted at least 1 week in advance with instructions for preparation for the visit prior to the visit by the monitor. We would like to thank you in advance for your co-corporation during this visit.

## Contacts

- For suggestions, please contact us at the email below: [garfield@tri-london.ac.uk](mailto:garfield@tri-london.ac.uk)
- For any site related issues please contact the site managers assigned to your individual site. They are your prime contacts for the day-to-day management of the study.
- Please continue to visit our website to keep abreast with our activities <http://www.tri-london.ac.uk/garfield>