Who can submit proposals?

Members of the Steering Committee and National Coordinating Investigators (NCIs)

National investigators enrolling patients in the registry will always do proposals in collaboration with a Steering Committee member or National Coordinator (See website for NCI list)

A non-investigator working in collaboration with a Steering Committee member and an investigator (e.g., expert in health economics)
Process for submitting a Proposal

Stage One:
Plan research question

GARFIELD SC, NCIs and national investigators
- Global analyses
- National analyses

Stage Two:
Electronic submission

GARFIELD website
Complete electronic submission form

Email acknowledgement, receipt of proposal

Electronic submissions stored

garfieldproposals@tri-london.ac.uk

Stage Three:
Proposal review

Proposal to Publication Committee for review

Steering Committee review
priorities for future analyses

NCIs / Investigators invited as authors

Stage Four:
Analysis & Authorship

Lead by designated first author(s)
ASF specification
Data analysis
Draft paper
Co-author review
Journal submission

UNRESTRICTED GLOBAL USE
http://www.garfieldregistry.org/

PUBLICATION/PRESENTATION
Stage One – Develop research questions

- A proposal from a national investigator may initiate a new collaborative effort with a Steering Committee member or National Coordinator.
- Before submitting a proposal, check the list of existing proposals on the GARFIELD website to confirm that your new proposal is not a duplication of an existing proposal.
- Consider:
  - Brief rationale
  - Research Questions
  - Analysis and comparison groups
  - Cohort(s) and study population
Stage Two – Electronic submission

- Go to the GARFIELD website to complete and ‘Submit a Proposal’

- The form comprises of the following lines:
  - Keywords
  - Working Title
  - Study Population
  - Co-authors/working group
  - Primary outcome
  - Secondary outcome
  - Brief rationale
  - Research Questions
  - Analysis and comparison groups
  - Cohort(s) and study population

- An automatic reply will generate an acknowledgement of submission

- All proposals and their status are stored on the website
Stage Three: Proposal review and prioritization

Timeline for acceptance of a proposal is usually up to two months:
1. The TRI team will notify authors if a proposal duplicates an existing proposal
2. The Publication Committee (PC) assesses bi-monthly the appropriateness of new proposals
3. Accepted proposals will be considered as part of list of potential topics for future analyses (for congress presentations and manuscripts)
4. The Steering Committee reviews twice a year the priorities for analyses over the next 12 months
5. NCIs and Investigators who have submitted proposals or expressed an interest in a clinical topic will be invited to be (co)authors
Considerations

Qualification for authorship

- The Publication Committee (PC) is central in chairing the scientific direction of each publication and verifying the project authorship
- Lead authorship of key GARFIELD publications (based on global data) will be the Steering Committee or nominated NCIs
- Investigators are limited to first authorship on no more than two papers in progress

High-priority papers

- The Steering Committee will review the list of all ongoing manuscripts at least twice each year, with special attention to high-priority classification. Criteria for classifying a paper as high priority include:

1. Scientific importance of potential findings
2. Potential impact of publication on the future of the GARFIELD-AF Registry
3. Potential for high visibility in wide circulation scientific journals
4. Urgency in making findings available to scientific community and/or public
TRI Publications Support Group

- **Publications Committee** will be assisted by a publications support group at the TRI, who will assist in daily administrative tasks and, when needed
  - Include roles such as the Lead Garfield-AF Statistician and Garfield-AF Medical Writer
  - Interact with registry investigators and National Coordinators to identify, consolidate, and facilitate publication and presentation opportunities on a national and global level
  - Responsible for publication plan management
From proposal to published manuscript – working with statisticians

Karen Pieper
Duke Clinical Research Institute, Durham, USA and Thrombosis Research Institute, London, UK
Stage Four: Analyses and Authorship

- Each publication proposal is fully described in an analysis specification form (ASF) that gives adequate statistical and technical details for an independent statistician to replicate the analysis.

- The details of the ASF are confirmed during a teleconference with the lead authors and statistician.

- Once the statistical report of results have been received, the lead author has 3-6 months in which to write the manuscript and circulate it to the PC for review.

- Milestones (deadlines) are generated by TRI, in discussion with all parties, for:
  - Data analyses
  - Draft paper
  - Co-author review and comment
  - Journal submission

Lead by designated first author(s)
ASF specification
Data analysis
Draft paper
Co-author review
Journal submission

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PUBLICATION/PRESENTATION

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Steps in the Analytic Process

- Topic is submitted, approved, and is at the top of prioritized list
- Request form is assigned to a statistician and programmer
- Statistical team has a conference call with the P.I. to clarify hypotheses, definitions, population of interest...
- Statistician writes a analysis plan which includes details of the above plus all proposed tables, figures and analyses
- Analysis plan is shared with the P.I. for sign-off
- All analyses are performed, a statistical report is generated, and the P.I. should now have enough data to write a first draft

From here it is an iterative process between the P.I., editor, statistician, co-authors and steering committee to take the paper to publication
Successful collaborations with statisticians include:

Quick response time

- When a statistician is waiting for answers to questions or new requests, they will have to move on to another project if your project goes dormant.
- After too much delay, the data will be outdated and time will need to be allocated to update to the latest data harvest.

Mutual learning

- Help the statistical team understand the clinical issues behind your question.
- The statistical team will be glad to talk to you about the statistical and data issues around the question.