Registry Assessment of Peripheral Interventional Devices (RAPID) Roadmap Working Group

Logistics: Key Steps to Operationalizing the Roadmap

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Friday November 6, 2015
ACC Heart House
Washington DC

Logistics and Operations

- June 5, Kick-off meeting at the FDA
  - 50 attendees, representing 20 organizations
    - Government
    - Industry
    - Academia and Healthcare
  - Defined RAPID objectives and phases
    - Phase I – Identify minimal set of core data elements for registry assessment of infrainguinal arterial devices
      - Phase Ia – Develop a method for registries to extract UDI data for relevant PVI devices
    - Phase II – Develop interoperable data extraction methods
    - Phase III – Apply a coordinated registries network to studies supporting a regulatory decision

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- Call for Working Group participants
  - June 5 meeting volunteers
  - Invited/recommended participants
  - Mailing list distribution to full MDEpiNet distribution list
  - Total Project team = 80 + and growing!!
- Rich with diversity in experiences and perspectives

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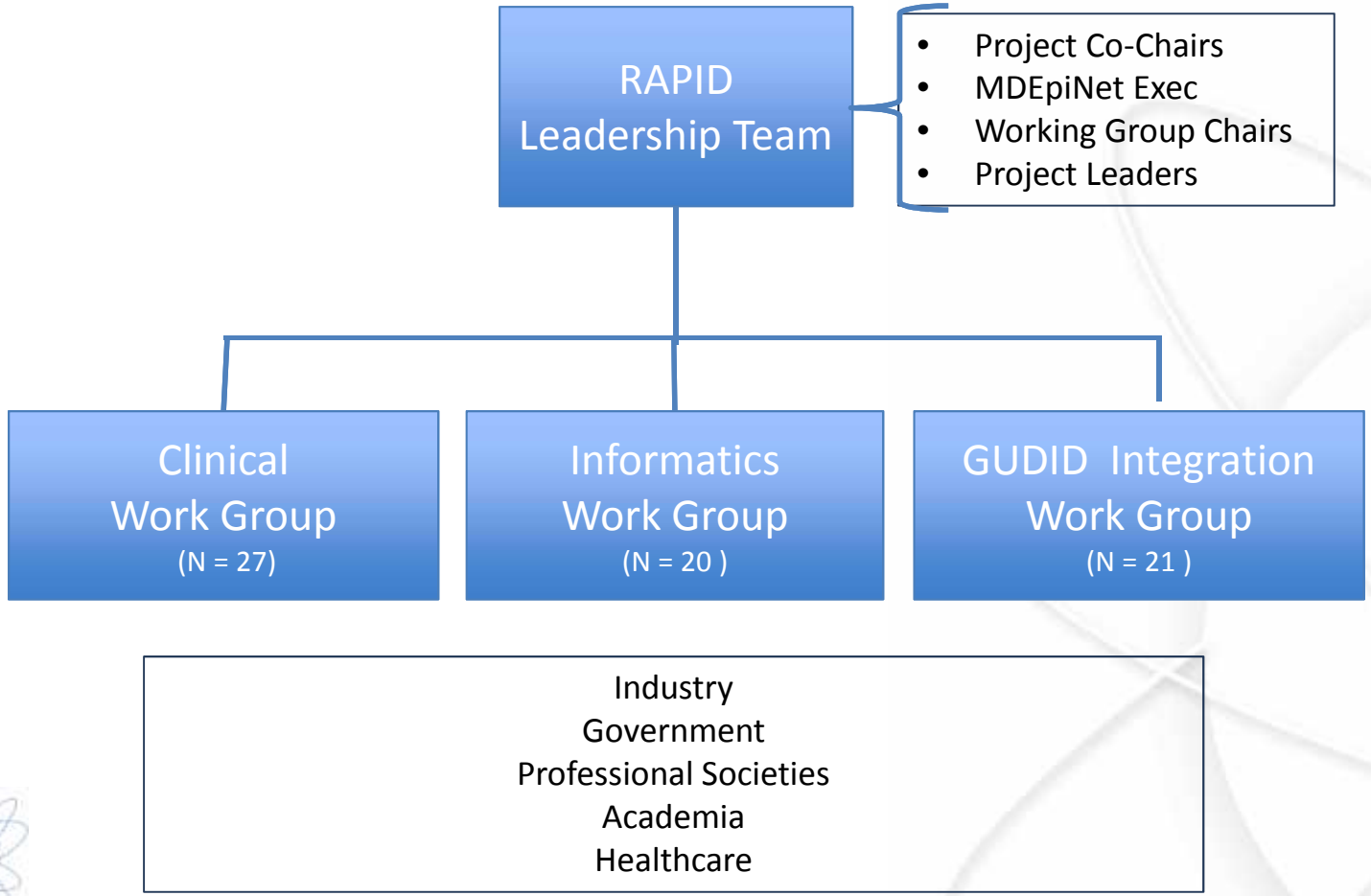
Organizational Structure



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- Communication Channels
  - MDEpiNet Website (*http://www.mdepinet.org/passion/*)
  - RAPID leadership meetings
  - Workgroup working meetings
  - On-line collaborative workspace (*https://flow.dcri.duke.edu/sites/mdepinet/WorkingGroups/SitePages/RAPID.aspx*)

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- Budget
  - Cost estimate for Phase I of $100-150K
  - Today we are requesting 10-15 partners to consider contributing funds and in-kind support from these and others.
  - If your organization will consider this please contact Rebecca Wilgus (rebecca.wilgus@duke.edu).

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- Purpose & Scope
  - To ensure the work is focused and deliverables are directly supporting end goal.
  - Phase I will focus on the RAPID ‘core’ components: PAD-specific and required by *all* the use cases; recognizing individual projects will need non-PAD and supplemental PAD data
- Use Cases
  - Prospective clinical trial, pre-market study
  - Post-market study, surveillance
  - Objective performance criteria creation
  - Randomized controlled trial of adjunctive pharmacologic treatment
  - ‘Living’, with additions and refinements added

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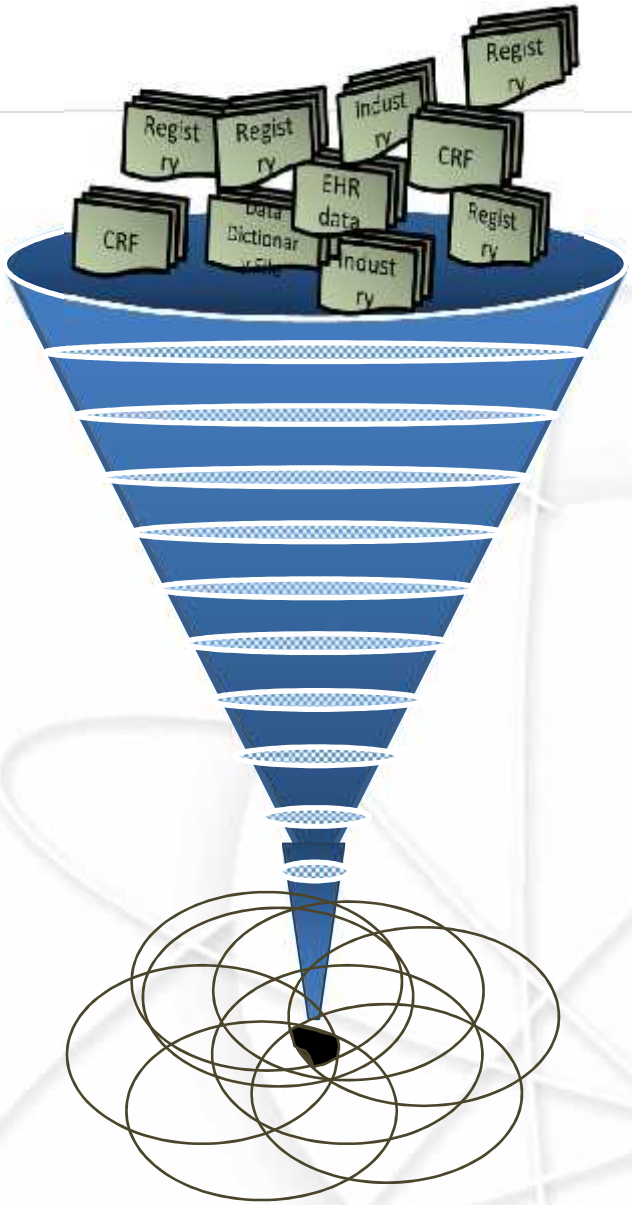
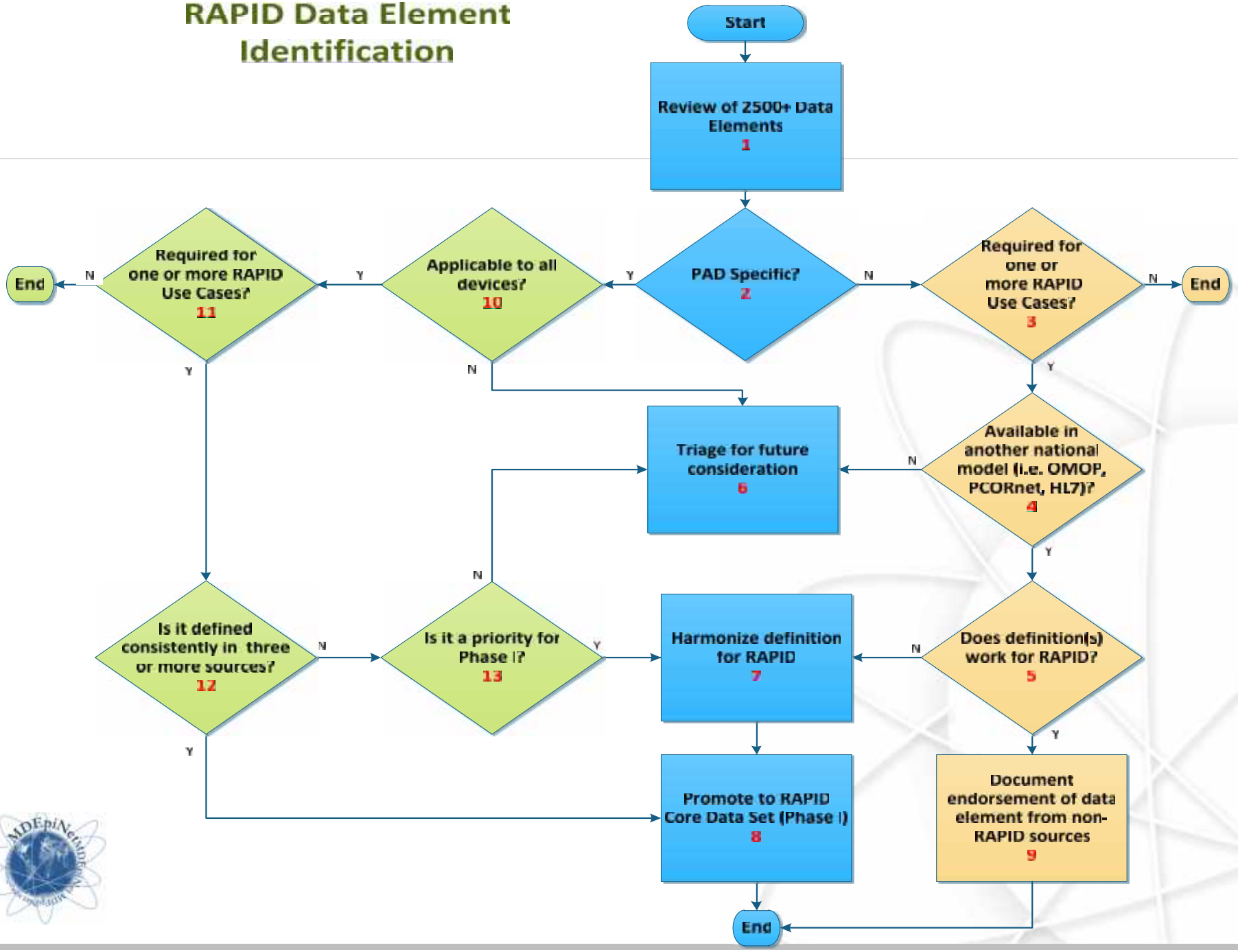
- Case Report Form Collection
  - Letters of request sent
  - 3 Registries & 5 industry partners have sent forms so far
  - Forms from other partners are pending
- Confidentiality
    - NDA template available on request
    - Sources of data elements are anonymized in the documents that will be used by WG's

Data Elements

- Summary to date
  - Nearly 3000 data elements from 7 sets of CRFs have been abstracted & categorized
- Goal: 100 Core PAD data elements



RAPID Data Element Identification



Complete Study Dataset