

FRAMING THE ROI FOR LINKED REGISTRY STUDIES

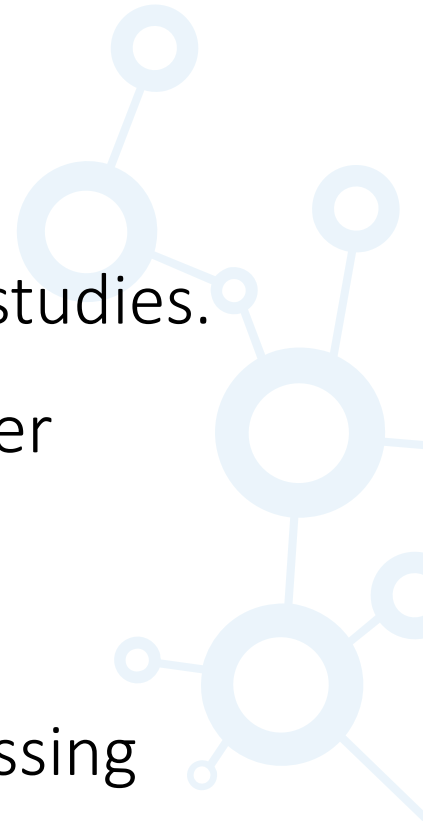
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Are linked registry studies “Better, Faster, Cheaper”?

- Documentation of faster enrollment exists
- Linked registry studies provide study populations that are larger and more representative of the population exposed to devices
- The issue of cost is complicated by the fact that we do not have an agreed upon method analyzing the cost of linked registry studies. We don't have a paper we can all point to that provides an understand of experience with linked registries and cost. We don't have a baseline to evaluate success of the future coordinating center in driving down the cost of studies.
- Another white paper may documentation of “better and faster.”

Scope of this meeting and proposed White Paper

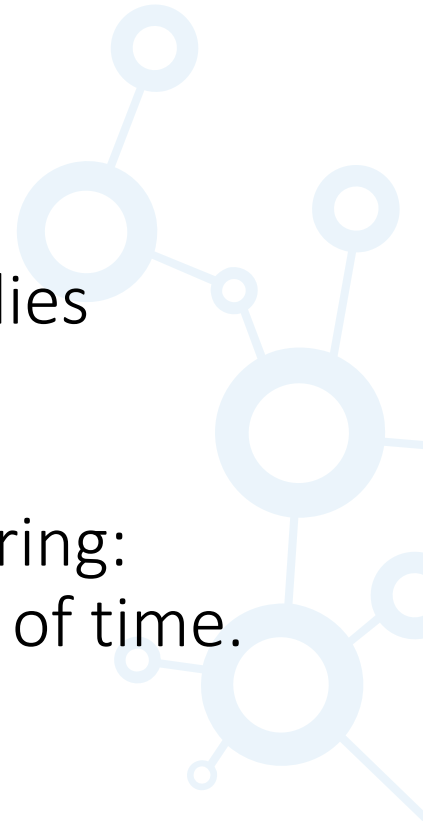
- The costs of doing linked registry studies compared to traditional studies.
- In the proposed white paper, a discussion section can present other potential benefits of linked registry studies, including
 - Effect on the pre-post market shift.
 - Faster to patients/market.
 - Less exposure to big recalls and law suits by finding and addressing problems sooner.
- I suggest we also talk about some of the limitations in the white paper.



Cheaper?

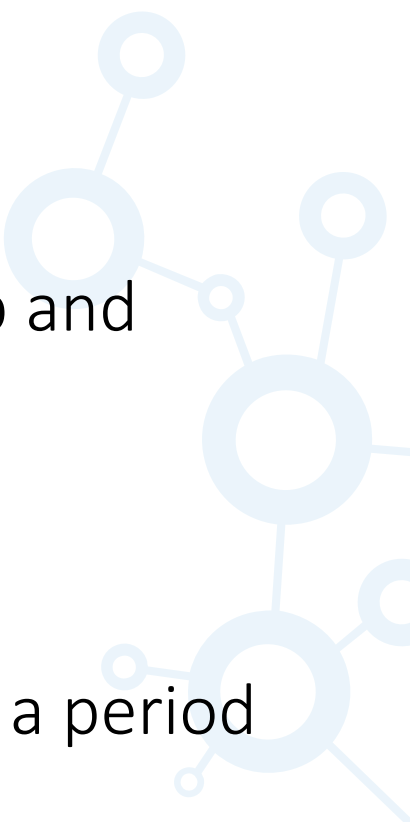
Issues created by the paradigm shift

- The paradigm shift from stand alone studies to linked registry studies makes it difficult to do a one-to-one comparison of study costs.
- Savings of doing studies in registries must be calculated by comparing:
 - The cost of setting up and maintaining a registry over a period of time.
 - The cost of comparable stand alone studies.
- The incremental cost of doing a linked registry study goes down as more studies are done.



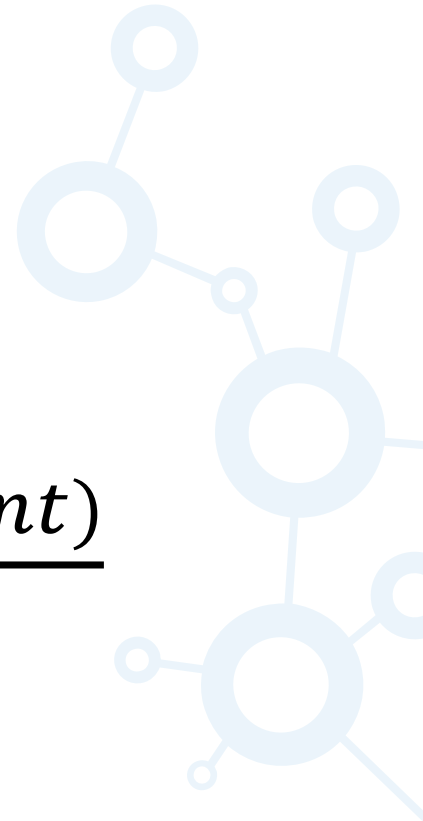
Cheaper?

Issues created by the paradigm shift

- At what point do we see a return on the investment of standing up and maintaining a registry?
 - How many studies over how many years?
 - Can we project how many studies might be done in a registry over a period of time?
 - ROI is a useful tool because we need to understand:
 - The up front investment of creating and maintaining registries.
 - The return in terms of cost-savings that investment makes possible.
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ROI definition

$$\text{ROI} = \frac{(\textit{Gain from Investment} - \textit{Cost of Investment})}{\textit{Cost of Investment}}$$




Cheaper? Estimating the actual cost of linked registry studies and framing the ROI

- ROI must understand all costs:
 - Standing up and maintaining registry.
 - Cost to clinical facilities reporting to registry.
 - Cost of linkage.
- Framing the ROI is critical. Investments for whom? Returns for whom?
 - “ROI to society” includes all costs and considers all cost savings.
 - “Cost to various partners” includes the cost to specific stakeholders and the savings to that stakeholder.



Cheaper? Compared to what?

- We are fortunate to have the Pew commissioned study by Resnic et. al on the cost of traditional post approval.
 - That paper will be released soon.
 - The results of that study may be useful to our ROI calculations, providing an estimate on the average cost of traditional studies.
 - Josh Rising from Pew will join us via phone during our working lunch to offer to work with us on the next phase of the white paper.
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My first rough calculation

- Worked out with Mike Mack, using numbers from TVT:
 - \$35 million dollars to stand up and maintain TVT over 5 years.
 - There have been 10 linked registry studies done with the TVT during that period.
- If we assume that each traditional study costs \$5-10 million Million.
 - Traditional methods: 10 x \$5-10 million = \$50-100 million.
 - Upper limit gain or savings = \$65 million.
 - Cost of investment = \$35 million.

$$\text{ROI} = \frac{(\textit{Gain} - \textit{Cost of Investment})}{\textit{Cost of Investment}} = \frac{(65 \textit{ mil} - 35 \textit{ mil})}{35 \textit{ mil}} = 0.86 \rightarrow 86\% \text{ return (upper limit)}$$

- The ROI of investing in a linked registry:
 - Linked registry studies cost from a third to half the cost of traditional studies.
 - In other words, traditional studies may be double the price of linked registry studies.

Limitations with my rough calculation

- I have not used a well specified frame-work.
- I have not considered costs to industry.
- I have included the investment of other partners that should not be in the model.
- I have not considered the cost to hospitals for providing the data, which would not be in the industry ROI but should be in a societal and/or hospital ROI.



Limitations: “society” frame

- While we can do a simple calculation, in reality society does not pay for the registries or the studies; societal costs and returns are aggregate.
- Many registries have multiple stakeholders that pay into the registries, with multiple use of the same data (quality initiatives, reports to CMS, etc...).
- Sustainability models of registries differ.
- The actual cost of a linked registry study for a sponsor must be separated out.

Cost = contribution to analysis + contribution to registry

Rough sketch of an ROI for industry

- Must include contribution of industry to stand-up and maintain the registry, plus cost to industry conducting linked registry studies.
- Cost of traditional studies for industry. Can we agree on an estimate? Will the Resnic paper provide us with those numbers?

Other issues to address

- For some case studies, we do not have enough data to show an ROI yet.
- Can we project the number of studies that will be done on a registry?
- Can we project an ROI based on anticipated or projected number of linked registry studies?
- As a group we need to decide the frame or frames for the ROI. I suggest we do an ROI for industry as a category. Societal ROI may be also done.

THANK YOU!

