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.

ROI definition

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

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.

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.

$$\text{ROI} = \frac{(\boldsymbol{Gain - Cost\ of\ Investment})}{\boldsymbol{Cost\ of\ Investment}} = \frac{(\boldsymbol{65\ mil - 35\ mil})}{\boldsymbol{35\ mil}} = 0.86 \rightarrow$$ 86% 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!