

Business process overview and due diligence checklist to assess new small business funding opportunities



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Foundations that fund medical research increasingly have and are taking the opportunity to fund biopharmaceutical companies, particularly (though not exclusively) small, early-stage companies that have difficulty raising capital elsewhere. Foundations feel acutely responsible for the stewardship of resources from donors small and large, and must engage in a rigorous process for making these decisions. We offer these tools and insights from TRAIN (The Research Acceleration and Innovation Network) members to assist in that process.

Most foundations engaged in this type of venture philanthropy concur that involving individuals with expertise in biopharma business development – whether on staff or outside consultants or expert volunteers – as well as legal counsel in this process is a necessity.

1. **Process.** What are the steps involved in making investment decisions, and who should be involved? The flowchart below was developed by the Foundation Fighting Blindness and shared with TRAIN at a workshop on [“The Nuts and Bolts of Cross-Sector Deal-making”](#) in 2012.
2. **Evidence/Documentation.** What specific information might you require of a potential awardee? The checklist below also comes primarily from input from Foundation Fighting Blindness, with gratitude to Brian Mansfield, deputy chief research officer, and Patricia Zilliox, chief drug development officer.
3. **Decision-making Criteria.** What are the factors that influence a final decision positively or negatively? In a *FasterCures* [Webinar](#), Lou DeGennaro, now the CEO of the Leukemia & Lymphoma Society, summarized the society’s diligence questions, outlined below:
 - Does this address an unmet medical need, or is this a crowded area supported by others?
 - What is the quality of the science and the asset, and what is the level of innovation?
 - What is the degree of competency and enterprise readiness of the partner?
 - What will be the value-add of involving the foundation as a partner?
 - Is this project a strategic fit with the foundation’s research agenda?
 - Is there a potential for a return on investment?

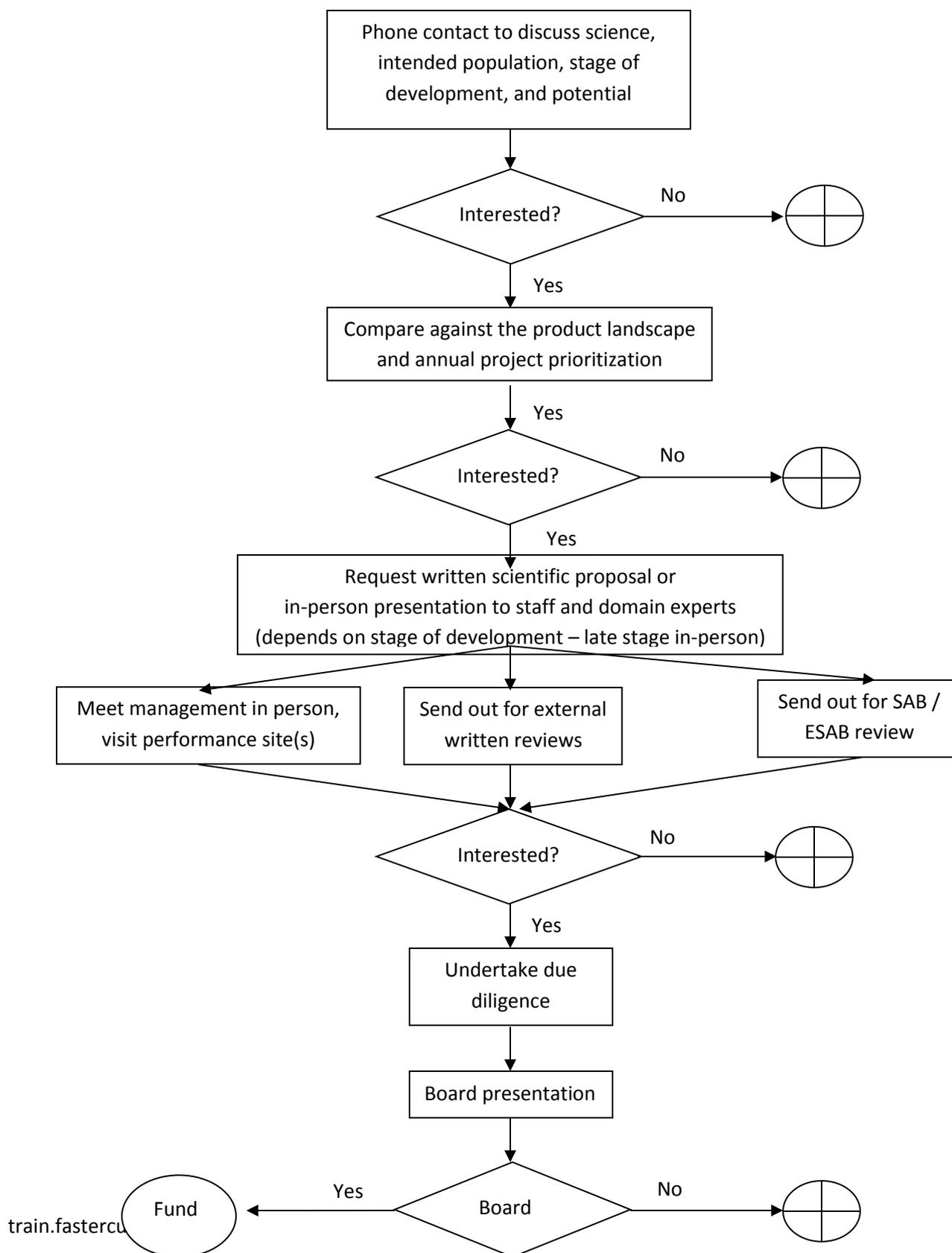
Parent Project Muscular Dystrophy describes its approach to partnerships with industry in great detail on its [Web site](#). In evaluating a potential investment in a company developing a clinical candidate, it is looking for:

- A solid scientific rationale demonstrating that the disease biology supports the method of intervention;
- A drug development plan that is good and feasible;

- Finances stable enough to see the company through the project;
- A reasonable business model and exit strategy (out-licensing, IPO, acquisition, co-development deal);
- A management team with the appropriate experience to move the project through to its value inflection point; and
- The right intellectual property package to support the exit strategy.

Overview of Process

(Source: Foundation Fighting Blindness)



Due Diligence Checklist for Co-Funding Discussions

(Source: Foundation Fighting Blindness)

1. Documents

- a. Company financials: Has the foundation reviewed the financial status of the company and understood what funds it has available, their source, and both current and future anticipated cash flow?
- b. License/option agreements if applicable
- c. Other applicable agreements: e.g. Is there anything else the technology is dependent on? Manufacturing?

2. Intellectual Property (IP)

- a. Current IP assessment: Has the foundation received a legal opinion on IP and freedom-to-operate (FTO)? (A full FTO search is very expensive and not usually appropriate; however, a higher level review of key issues and legal opinions is sought.) Attach written opinions from company counsel. Summarize conclusion – Is there a clear path? What are the most likely risks? What licensing is required?
- b. Prosecution plans for existing IP in U.S. and rest of world
- c. New IP: Will the foundation's investment help develop new IP? Does the foundation have walk-in rights if the IP is not used or licensed? Does the foundation benefit from licensing of IP it co-funded?

3. Development Plans

- a. Overall development and clinical plan with costs, timelines, milestones, deliverables, and go/no-go decisions
 - i. Target Product Profile and current stage of development. What is known about the mechanism of action or pathway involved? Is there any efficacy or safety data? Validity and relevance of any animal models used. Is the route of administration clear? Is there any formulation data? Is there a chiral center – is chiral purity a concern for manufacturing? Is this the lead, or what is the status of lead optimization? What is the anticipated timeframe to Investigational New Drug submission to FDA?
 - ii. Primary use of foundation funding, definition of deliverables along with milestones and payments at each milestone, anticipated stage of development upon funding termination, likely need for additional foundation funding at the end of the project
 - iii. Who is, or might, co-fund this project?
 - iv. Clinical development path – phase, randomized, blinded, study objective, timeline, primary and secondary outcome measures, estimated enrollment, eligibility
 - v. Reproducibility and validation
- b. Overall commercialization plan
 - i. Product category and name
 - ii. What is the nature of the product and its intended use?
 - iii. Product market size (company and foundation perspectives). This is further refined by understanding the stage of disease that can be targeted, the size of that more targeted population, whether the therapy will slow, stop, or reverse disease.

Formulation and dosing can impact numbers – daily oral meds represent more product sales than a once a month therapy for instance

- iv. Product cost (company and foundation perspectives)
- v. Does the foundation have a clear understanding of how the product would fit into the existing commercial landscape?
- vi. Competitive landscape analysis: Competitors, their similarities and differences, strengths and weaknesses, stage of development

4. Regulatory

- a. Overall regulatory plan by country
- b. Name of regulatory counsel
- c. Comments on any FDA interactions to date: Nature of the meetings, topics discussed, outcomes, any written feedback provided by FDA

5. Human Resources at the Group to Be Funded

- a. Internal team members, backgrounds, status (employee/contract)
- b. Contract groups being considered (contract research organizations, distributors, etc.)
- c. Has foundation met face-to-face with senior management? Details and impression

6. Commercialization/Exit Plans: Does the company have the capability to commercialize? If not, what is its exit strategy?

- a. Plans beyond foundation funding. Attach company business plan.
- b. Introduction dates
- c. Sales projections by territory/indication
- d. Average selling prices/cost of goods
- e. Profit and loss/net present value assessment