

Partnering with Non-Profit Funders: Research to Commercialization



Presenters

**Felice Lu, Research Policy Manager, Research Policy Analysis and Coordination
University of California Office of the President**

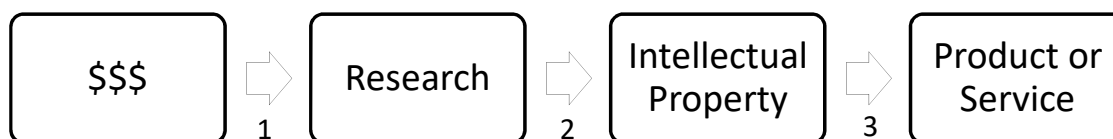
Reviewed and/or negotiated hundreds of research agreements with non-profit funders containing a wide range of intellectual property policies; leadership team for the Non-Profit Funder Research Institution Partnership; previously licensing at University of California, San Francisco

**Mark Allegretta, Vice President, Research
National Multiple Sclerosis Society**

Provide leadership and direction for the Society's commercial and domestic research portfolio, including partnerships developed through Fast Forward. PhD from Univ. of Vermont, post-doc at Stanford as National MS Society fellow; positions in InterMune Pharmaceuticals and Connetics Corporation



Research to Commercialization



- Step 1: Execute a funding agreement that enables downstream commercialization of intellectual property
 - Tech transfer role may vary
- Step 2: Magic?
- Step 3: Partner with non-profit funder to protect and license intellectual property
 - Funder's role may vary



If you've worked with one non-profit,
you've worked with ~~them all.~~
one non-profit.



Agenda

- A. National MS Society approach to intellectual property
- B. Section by section discussion of National MS Society IP policy
- C. Partnering with National MS Society after an invention has been created
- D. Non-profit Funder Research Institution (NFRI) Partnership



A. National MS Society Approach to Intellectual Property



A. National MS Society Research Scope

The National MS Society is the largest non-government funding agency for MS research



\$1.06 billion deployed

- 4,861 Research Grants, Fellowships, **Fast Forward** commercial funding and other awards in diverse areas including autoimmune, neurodegeneration, rehabilitation and wellness

The National MS Society leads the global effort to bring diverse groups together for a common purpose



€20 million Progressive MS Alliance

- 15 global member organizations
- Leveraging €60 million total

The National MS Society has played a central role in catalyzing formation of the **International Progressive MS Alliance**. The Society likewise is a leader in managing the strategic directives of the Alliance, representing the collective effort of global MS advocacy groups from 15 countries.

- Approximately **\$34 million** FY2019 commitment to new projects, creating a multi-year commitment of approximately **\$87 million** through FY25

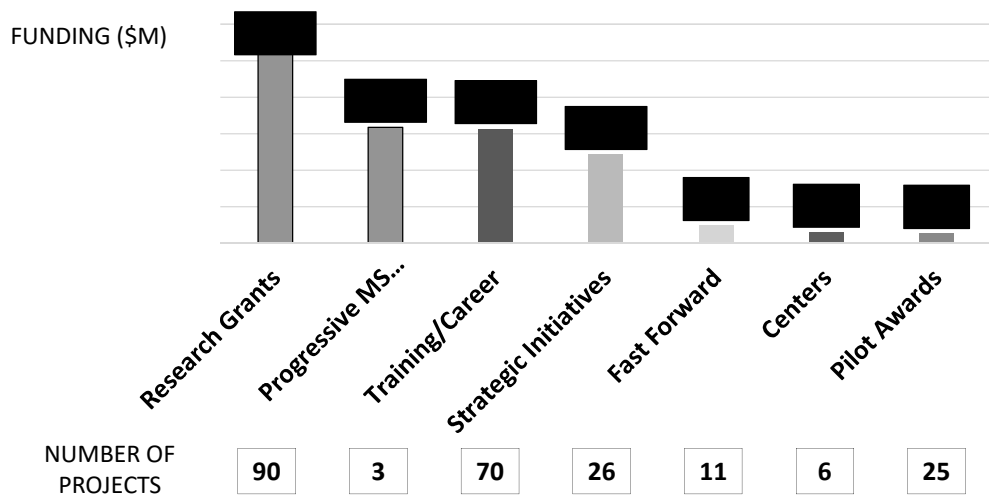


A. Funding process

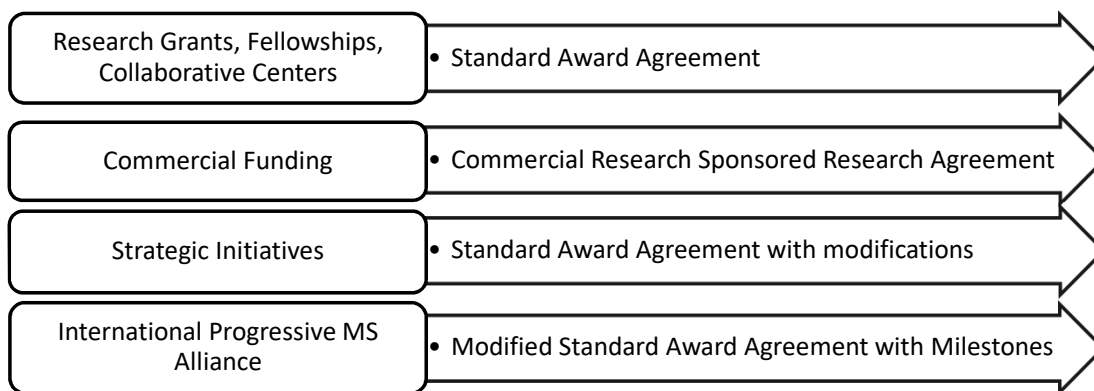
- Society award agreement last established in 1980's; revised 2019.
- **Fast Forward** commercial funding program developed in 2008
- Role of Advisory Committees
 - Research Programs Advisory Committee
 - Commercial R&D Board of Advisors
- How the Society engages funded entities has evolved
- What are the principles guiding Society's approach?
- Is Society's approach to IP similar to other non-profits?



A. Funding Commitments by Program



A. Agreements by program



B. Details of National MS Society IP Policy



B. Society IP Policy Clause (a)

a) All Results are owned by the party that generates them. All investigators working on the Project shall assign to the institution that employs them any title and interest in the Results.

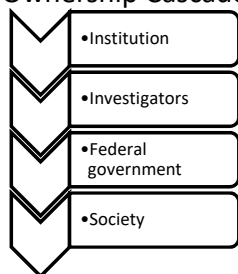
- ✓ Institution ownership of intellectual property is required by most funders, including state, federal, and industry funders
- ✓ Definition of “Results” varies between funders, and Institutions’ ownership policies vary in terms of types of property assigned
 - Patentable inventions
 - Copyrights
 - Tangible research materials
 - Data
 - Knowledge



B. Society IP Policy Clause (b)

b) In the event Institution waives its intellectual property rights relating to Results and elects to not assign rights to the investigators involved with the Project then the Institution shall, to the extent permitted by law, promptly assign all rights in and to such Results as directed by the Society.

Ownership Cascade



- ✓ Knowledge, know-how, ideas and other types of intellectual property can be owned by the investigator if not owned by the Institution
- ✓ Increasingly seeing multiple non-profit funders funding the same invention – where is their position in the cascade?



B. Society IP Policy Clause (c)

c) All Results and intellectual property funded, in whole or in part, by the Society shall be reported in confidence to the Society by the Institution within one month of their disclosure to the Institution. Both Principal Investigator and Institution will make reasonable efforts to refrain from any action that might impair the ability to obtain patent or other intellectual property protection for Results.

- ✓ Funder recognizes the confidential nature of new technologies
- ✓ Funder requires that researchers refrain from making public disclosures that impact patentability



B. Society IP Policy Clause (d)

d) The Society shall receive a share of revenue and consideration received as a result of the commercial exploitation of any Results by entering into a revenue sharing agreement at the time of or prior to such exploitation. Such revenue sharing agreement shall provide that the share of income allocated to the Society shall be calculated in good faith, taking into account the economic contribution of the Society, in proportion to any other economic contributions in obtaining such Results, after deductions of reasonable out-of-pocket expenses.

- ✓ Revenue sharing agreement only needed if 1) invention is made and 2) the invention will be licensed
- ✓ Society share is proportional to its contribution
- ✓ Out-of-pocket patenting and patent defense expenses deducted



B. Society IP Policy Clause (e, part 1)

e) The Institution shall take appropriate steps to commercialize Results in a timely fashion through identification of a licensee. The Institution shall include provisions in all exclusive licenses requiring diligent commercialization of the Results, setting appropriate milestones to measure licensee effort and performance and permitting cancellation of the license (or conversion of the license to a nonexclusive license) in the event the licensee fails to achieve the required performance levels.

- ✓ Diligence requirement consistent with Point 2 of AUTM-endorsed *Nine Points to Consider in Licensing University Technology*
- ✓ Funder diligence requirement provides strong counter-argument in negotiations with potential licensee



B. Society IP Policy Clause (e, part 2)

e) If the Institution has not taken effective steps to commercialize Results through licensing or assignment, within five years after a patent issues relating to such Results, the Institution shall enter into negotiations with the Society, or its designees, to assign title unless prohibited by law or unless the Institution can show reasonable cause as to why it should retain title.

- ✓ Institution is first to attempt to commercialization, but if those efforts fail after a reasonable period of time, Funder has chance to commercialization
- ✓ Assignment (or exclusive license) should reserve rights for University to use Results for research and educational purposes



B. Society IP Policy Clause (f)

f) The Institution shall report annually to the Society under confidentiality, after the first anniversary of a patent application filing, on any additional Results or applications and for the duration of the patent term, on its commercialization efforts resulting from funding by the Society, including the names of current licensees (if such licensee agrees), the relevant terms of any licenses (redacted if necessary), and the receipt of any royalties or other licensing consideration due under such licenses.

- ✓ Yearly progress and financial reports required
- ✓ Additional information provided to funder subject to licensee input



C. Partnering with the National MS Society



C. Partnering Challenges and Opportunities

Challenges

- Developing technologies across diverse disciplines
- Setting realistic expectations
- Increased risk aversion in the academic sector
- Appreciating the perils of public disclosure
 - Implement reporting safeguards and increase communication

Opportunities

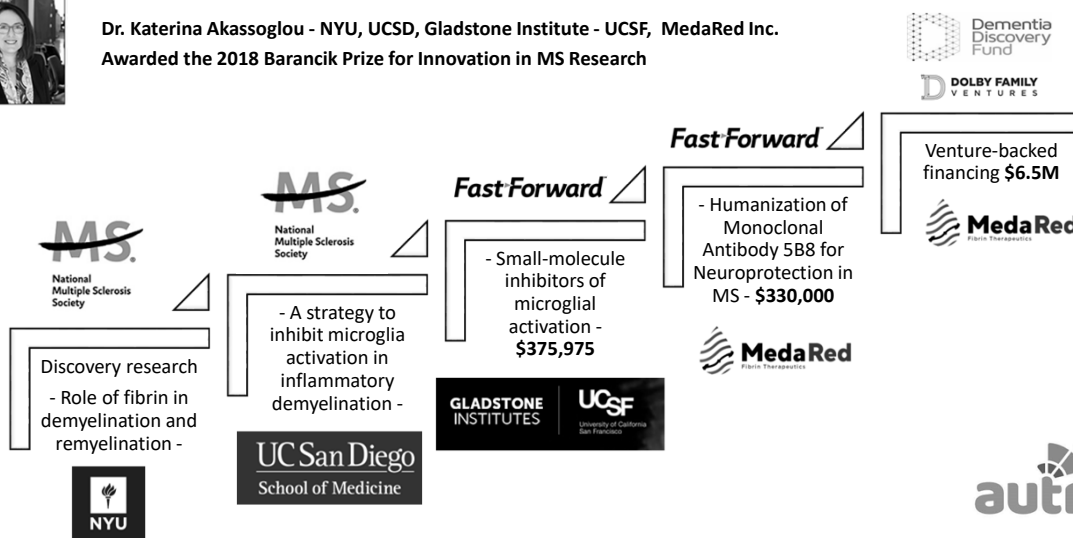
- Improved translational research brings business development expertise
- Institutions with internal business development centers tend to understand the space well



C. Discovery to Commercial Development



Dr. Katerina Akassoglou - NYU, UCSD, Gladstone Institute - UCSF, MedaRed Inc.
 Awarded the 2018 Barancik Prize for Innovation in MS Research



D. Non-Profit Funder Research Institution Partnership



D. Non-Profit Funder Research Institution Partnership

- Goal: Establish a framework that encourages long-term effective collaborations between non-profit funders and research institutions
- History:
 - Informal discussion began around intellectual property topics in 2012.
 - In 2017, the NFRI partnership was formalized as a collaboration between the Health Research Alliance (HRA) and the Council on Governmental Relations (COGR).
- NFRI Workgroups:

Intellectual Property
and Tech Transfer

Research Project
Support Costs

Streamlining
Administrative
Requirements

<https://www.healthra.org/nonprofit-funder-research-institution-partnership-nfri/>



D. NFRI IP and TT Survey May 2018

Non-Profit Funder Challenges

Operational

- Should funder negotiate case-by-case or set a firm policy?
- Shortage of internal expertise and funding for legal counsel
- Board mandates certain terms that are non-negotiable

Licensing

- Reporting lapses by research institutions
- Desire to maximize impact of work, making sure treatments reach patients

Royalty Sharing

- Strengthen right to royalties and participate in future equity rounds
- How to recoup funder's investment if an invention is commercially licensed
- What is a reasonable ask?

Patient Benefit

- Desire to maximize impact of work, making sure treatments reach patients



D. NFRI IP and TT Survey May 2018

Research Institution Challenges

General

- Non-negotiable IP terms, unwillingness to find “middle ground”
- Compliance with obligations being imposed on research institution
- State laws create challenges in accepting some funder IP policies
- Do the funder’s requirements compromise the research institution’s mission?

Licensing

- “March-in” provisions hinder licensing negotiations
- Lack of knowledge of research institution licensing practices
- Non-exclusive royalty free licenses and the resulting impact on commercial interest in inventions
- Non-profit funders’ partnerships with for-profits, where lower indirect costs are paid but full commercial rights are provided to for-profit

Royalty Sharing

- Demands for return on investment in excess of contribution
- Lack of recognition that IP may have been funded through multiple funding sources



D. NFRI IP and TT Subgroups

Definition of Invention

- Drafted definitions of background IP and foreground IP and principles for the treatment of these in research contracts

Control of Licensing

- Drafted principles and guidelines document covering:
 - Control vs communication
 - Pre-licensing issues including strategy, negotiation, reviews/approvals
 - Post-license issues including licensee progress and march-in rights

Royalty Sharing

- Assembled, reviewed and discussed 40+ royalty sharing clauses
- Drafted “Principles & Guidelines for Royalty Sharing”

Patient Access

- Researched patient access programs that improve treatment affordability, availability, and geographic accessibility
- Discussed roles of funders and research institutions in encouraging treatment of orphan diseases and access to treatments in developing countries
- Draft guidelines in progress



D. More information on NFRI IP and TT progress

<https://www.healthra.org/nonprofit-funder-research-institution-partnership-nfri/>

- AUTM Annual Meeting, March 9, 2020 San Diego Workshop 10:45-12:15
- Join the NFRI partnership: next meeting spring 2020, Washington DC
 - Finalize subgroup deliverables
 - Present deliverables to larger group
 - Merge deliverables into a cohesive toolkit
 - Discuss outcomes with external audiences



Questions?

