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INTELLECTUAL PROPERTY CONSIDERATIONS

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Drug development contracting will be easier if the Foundation controls the intellectual property relating to the drug candidate



Fundraising for clinical development may be facilitated if the program has commercial prospects (and supported by patents)

Generating Intellectual Property



Types of intellectual property:

Patents

Know-how: Results of studies, tools and materials (e.g., cell lines, reagents developed)



Potentially patentable subject matter:

Novel drug structures for treatment of disease

- Gene therapy construct
- Antisense Oligonucleotide / siRNA
- Gene editing constructs (gRNA)

Intellectual Property Generation: Sponsored Research



U.S. academic institutions will have intellectual property policies that require the University to own IP generated using the institution's resources (including with government grants)



Institutions outside the U.S. may be more flexible regarding IP ownership



Incorporate IP terms into the SRA to provide desired IP rights

Sponsored Research Agreements: Intellectual Property Terms

Non-exclusive right to use the results and research tools for Research and Development (with right to sublicense)



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Option to negotiate an exclusive IP license for commercial purposes

Inventions and patent filings should be reported to Sponsor (may require Sponsor to pay for any patent filings)



If there is a basis for inventorship by the Foundation, coownership of intellectual property could result

Freedom-to-Operate



Freedom-to-operate (FTO) refers to the resolution of any third-party intellectual property rights (i.e., all required third party rights are licensed, acquired, or expired)

Timing for FTO is usually commercial drug launch (clinical activity is protected by safe-harbor)

QUESTIONS/COMMENTS?

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