Mallinckrodt Pharmaceuticals – Washington University Collaboration

Call for Program Grant Proposals

Washington University and Mallinckrodt Pharmaceuticals have jointly developed two grant programs; Program Grants and Challenge Grants. Program Grants are geared towards projects that have a high likelihood of moving into the clinic within the 1-2 years. Challenge Grants are intended for earlier stage projects where a compelling therapeutic target has been identified, but additional validation is required. Neither of these programs requires that a therapeutic agent has already been identified. Specific areas of interest currently include: rare and severe or critical diseases, especially in the fields of autoimmune disorders, hepatology, neurology and nephrology.

Program Grant Awards

Program Grants are intended to provide multiyear support to projects likely to advance new therapeutic options that are aligned with Mallinckrodt’s research priorities. Preference will be given to principal investigators, or teams of investigators that have identified compelling targets for a milestone-driven program that progresses potential candidates toward *investigational new drug*-enabling studies (IND1). Progress will be assessed annually, with continued funding contingent on successful completion of milestones. Total resources requested should be adequate to accomplish the program goals and combined direct and indirect costs should not exceed $750,000 per year.

Program grant awardees will have access to Mallinckrodt’s extensive pharmaceutical drug development expertise. In addition, Mallinckrodt’s Hazelwood facility is prepared to offer In-Kind services to accelerate Program Grant objectives.

Program Grant Requirements

* **Strong scientific rationale**
* **Potential for novel, differentiated therapeutics**
* **Established link between target biology and disease mechanism**
* **Generates data to enable IND applications**

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Submission Process

Washington University faculty working on projects that meet our criteria are encouraged to apply. The first step is a three to five page, non-confidential [pre-proposal. Pre-proposals should describe the therapeutic approach and explain how funding will accelerate the translational research process to bring candidate therapeutics to the clinic.](https://ncats.nih.gov/files/cti-pre-proposal-template.doc) A provisional timeline with project milestones should be provided. Possible opportunities for In-Kind Services from Mallinckrodt R&D should be identified.

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| **Step** | **Contents** | **Due Date** |
| RFP Publication |  | TBD, target 4Q18 |
| Pre-Proposal | 3-5 Page non-confidential summary |  |
| Invitations to submit Full Proposals |  |  |
| Full Proposal | Comprehensive project description including budgets & timelines. |  |
| Face to face program presentations for finalists | 60 minute presentations with 30 minutes for questions and discussions |  |
| Award Decisions Announced |  |  |
| Programs Launched |  |  |

About Mallinckrodt

Mallinckrodt is a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. Headquartered in Staines-Upon-Thames, UK with research facilities in St. Louis MO, Madison WS and Dublin Ireland and offices in Bedminster, NJ, Mallinckrodt is a research-based company dedicated to serving patients with a wide range of serious and complex conditions. To learn more about Mallinckrodt, visit [www.mallinckrodt.com](http://www.mallinckrodt.com).

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| **Mallinckrodt-Washington University Pre-Proposal** |

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| --- | --- |
| Applicant’s Name: |  |
| Applicant’s E-mail Address: |  |
| Program Grant Title: |  |
| Applicant(s) Biographical Sketch: |  |
| Type of grant (Program or Challenge): |  |
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| Abstract (Brief statement summarizing program grant proposal) |

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| Introduction |

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| Description of the therapeutic target: |  |
| Key differentiating features: |  |
| Potential for new intellectual property: |  |
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| Preliminary results and supporting evidence (brief description of current data) |
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| Research Summary |

|  |  |
| --- | --- |
| Overview of project objectives: |  |
| Provisional timeline: |  |
| Potential in-kind services from MNK R&D: |  |