DRUG DISCOVERY AND DEVELOPMENT RELEVANCE GUIDELINE

1. Drug Discovery and Development Relevance

The mission of the McGill CIHR Drug Development Training Program (DDTP) is to train students in all aspects of drug discovery and development. While all students from the laboratories of DDTP mentors meeting eligibility requirements can apply, the relevance of their assigned project(s) to the field of drug discovery and development is a *sine qua none* for their selection as DDTP awardees. Likewise the relevance of a given conference/meeting to drug discovery and development is the primary requirement for the DDTP travel award competition.

In each competition, priority will be given to students working on projects or seeking to attend meetings that have direct relevance to drug discovery and development. Thus, the onus is on the applicant and his/her supervisor to make a case for the relevance of his/her project to the DDTP. The current guideline describes eligible areas of research deemed relevant to the DDTP competitions.

1.1. Research Project Relevance

Relevance is considered within 11 categories:

- Drug design and synthesis
- Process chemistry
- Target identification and validation
- Toxicology
- Pharmacokinetics and metabolism
- Development of tools for drug discovery
- Drug formulation and delivery systems
- Bio-engineering
- Development of animal models
- Drug related clinical research

- Combination therapy

Drug design and synthesis

Under this category, molecular modeling or rational drug design, total synthesis of a bioactive agent, structure modification for enhancing bioactivity, stability or water solubility are considered relevant. In cases where the project is limited to the synthesis of a bioactive drug, an effort to collaborate with another investigator with the appropriate expertise for biological testing is encouraged.

Process chemistry

Research on any methodology development toward efficient synthesis of a drug or a class of drugs is relevant. This includes (but is not restricted to) the design of expedient, green or cost-efficient synthesis of drugs and the design of scalable synthesis. This does not include total synthesis of natural products unless the proposed synthesis is adaptable to large scale production of drugs.

Target identification and validation

Under this category, work on specific proteins (e.g. receptors, enzymes, transporters, etc) are considered relevant only if evidence of a potential therapeutic benefit for the treatment of a given disease is described. Target-directed proteomics, chemical proteomics projects, and signal transduction studies are deemed relevant.

Toxicology

Research projects on aspects of toxicology that are related to drug safety or drug effect on normal cells or tissues are considered relevant. Environmental toxicology is not relevant unless it is related to process chemistry.

Pharmacokinetics and metabolism

Under this category, any project on pharmacokinetics of a clinical drug *in vitro* and *in vivo* are considered relevant. Likewise, projects in drug metabolism *in vitro* and *in vivo* are acceptable.

Development of tools for drug discovery

Any method or assay development project that has the potential to accelerate drug discovery is eligible. Under this category, *in silico* analysis and molecular modeling are considered relevant.

Drug formulation and delivery systems

Nanotechnology directed at drug delivery, design and development of inhibitors of drug efflux pumps or any transporters are eligible. Any project dealing with controlled release of a drug with the purpose of enhancing bioavailability is deemed relevant.

Bioengineering

This category includes the design and engineering of new materials for drug delivery like new polymers, nanotubes, DNA cages, patches etc. The word delivery has to be understood from a pharmacokinetic standpoint.

Development of animal models

Projects on the development of new animal models, or improvement of an existing model designed to study a pathological pathway or to evaluate the toxicology or efficacy of a new drug, are considered relevant. Likewise, animal models to be used tools for imaging or pharmacokinetic studies fall in this category.

Drug related clinical research

In this category, clinical studies designed to determine the pharmacokinetics, the mechanism of action of a drug in human tissues and clinical pathology studies related to drug effects are considered relevant.

Combination therapy

Projects studying the combined effect of drugs (e.g. drug combinations for cancer treatment, AIDS tri-therapy etc.) or combination of a drug with interventional treatments (e.g. radiation + drug, photo-activated chemotherapy) are considered relevant. For interventional treatments (e.g. radiation, phototherapy), eligibility will be restricted to projects in which the drugs used in the intervention are the main focus of the application.

1.5.2. Eligible Conferences for DDTP Travel Awards

The DDTP travel award is to encourage trainees to go to conferences where they will learn about drug discovery and development. Both the relevance of the conference and the abstract to drug discovery and development will be assessed.

The applicants must demonstrate the relevance of the event to their project by providing the necessary information (e.g. links to event website, participating researchers, etc).

1.5.3. Relevance Statement in the Application Form

In all cases, the onus is on the student and supervisor to emphasize the relevance of their projects to drug discovery and development. It is the student's responsibility to select the appropriate relevance category on the form and to justify their choice in the appropriate box.