



### An Innovative New Commercialization Engine

The International Consortium on Anti-Virals (ICAV) is a not-for-profit drug development company dedicated to accelerating the discovery, development and delivery of novel anti-viral therapies for neglected and emerging viral diseases through the international collaboration of scientists, government and industry.

ICAV bridges the gap between academic research and commercial development by securing resources, funding POC experiments, providing strategic intellectual property advice and tailoring a development strategy for each lead candidate. ICAV harvests promising drug candidates for clinical development from its international network of over 200 scientists from 24 countries, leveraging resources to accelerate commercialization and adding value for future licensees.

This poster describes the ICAV process and presents a case study of an ICAV lead candidate.

**Vision:** Global Access to affordable anti-viral therapies for neglected and emerging viral diseases.

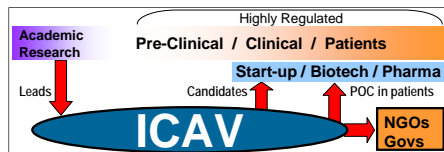
**Mission:** Through the international collaboration of scientists, government and industry, ICAV accelerates the discovery and development of novel anti-viral therapies.

**Goal:** The delivery of one novel anti-viral drug to market every five years.

### The Anti-Viral Commercialization Gap

Effective and readily available anti-viral therapies are an essential element of global health. A first line of defence against emerging pandemics, anti-virals can also provide effective treatment for diseases for which a vaccine does not exist or is not sufficient, such as HIV/AIDS, Dengue fever and pandemic influenza (e.g., H5N1).

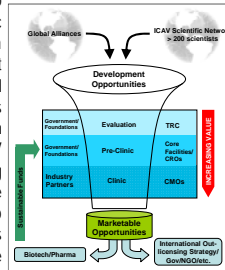
Traditional commercial approaches to drug development have failed to yield an adequate pipeline of anti-viral drugs, resulting in an urgent need for new therapies: Pharmaceutical companies have been hesitant to spend development dollars on diseases that primarily afflict the developing world; innovation has been hampered by an academic environment that is not tailored to the unique demands of drug development; venture capital has shied away from investments in early-stage development. As such, it has become increasingly difficult to find the resources and expertise to bring promising candidates from the laboratory to the clinic.



ICAV bridges the anti-viral gap by connecting academic research to drug-development expertise.

### The ICAV Commercialization Solution

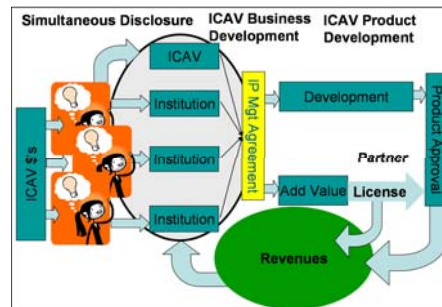
ICAV bridges the anti-viral gap by connecting promising academic research directly to an experienced drug development team, providing the resources and expertise to move drug candidates from the discovery stage through the regulatory process. ICAV provides the necessary funding and expertise to complete the "translational research" required to convert academic opportunities into the mid- to late-stage compounds desired by the industry.



ICAV functions as a two-stage process. First, the ICAV Senior Management Team vets discovery-stage candidates from academic labs through an Initial Review of Opportunity (IRO) and supports POC experiments for the most promising candidates. Candidates with viable activity at POC are then given to the Technical Review Committee (TRC). The TRC—an ICAV innovation composed of industry experts—further evaluates compounds and constructs a development plan encompassing all aspects of the drug development process, including non-clinical safety, pharmacology, formulation development and manufacturing, and clinical development. Resources are sourced along the way from CMOs, CROs, and the ICAV global scientific network.

### Intellectual Property Policy

ICAV will follow standard practice in obtaining intellectual property from research institutions and out-licensing agreements with third parties. ICAV will negotiate exclusive, worldwide licenses with commercial partners which will ensure that products will be available to lower- and middle-income countries (LMIs) at affordable prices. Where commercial sublicensees are executed, institutions will benefit from royalties on sales by the commercial partner.



ICAV licenses promising candidates from academic institutions offering comparable licensing terms to any commercial entity, including upfront payment, milestones and a royalty stream.

### Benefits of Working with ICAV

**Focused Development.** By focusing exclusively on anti-virals, ICAV galvanizes expertise and improves efficiency compared with Pharma and biotech.

**Access to Resources.** ICAV offers easy access through its international scientific network to a wide variety of resources essential for expediting the development process, such as animal models and cell lines for a variety of diseases.

**Expert Advice.** ICAV facilitates the translation of industry, regulatory, and IP advice from the Technical Review Committee to PIs, bridging a crucial gap in the drug development process.

**Funding.** ICAV funds specific, milestone-driven research to accelerate the clinical development of lead candidates.

**Drugs to Those Most in Need.** ICAV's mandate as a not-for-profit is to ensure the availability of novel anti-viral therapies to those most in need. By its arrangements with institutions and commercial partners, ICAV will ensure the availability of affordable anti-virals worldwide.

### ICAV Team

Together, the ICAV Team has over 200 years of biomedical research and development experience including leaders in both academia and industry.

#### Technical Review Committee

- Pre-clinical – Isobel Ralston, Torealis Research Inc.
- Regulatory Affairs – Ann Tomalin, CanReg Inc.
- Biostatistics – Miklos Schultz, SciAn Services Inc.
- Formulation & Manufacturing – Theo Anucha, ValuGen Pharma
- Market Analysis – Saul Ship, Ship & Assoc. Inc.

#### Senior Management

- Jeremy Carver – CEO/CSO
- Michel Chrétien – International Partnerships
- Dale Cumming – Scientific Evaluation/Pre-Clinical POC
- Denis Ferkany – Corporate Strategy
- Wendy Hill – Clinical Development
- Linda Kurdydyk – Intellectual Property
- Nathaniel Lewis – Communications

### WANTED: Anti-Viral Drug Candidates!

ICAV has funding from the Public Health Agency of Canada to evaluate and begin development of novel pandemic influenza therapies. ICAV is actively seeking promising lead candidates for further development. As such, ICAV is putting out a call to all tech transfer offices across Canada and around the world. We are also interested in candidates for other viral diseases, such as Dengue fever, HIV/AIDS, hepatitis, etc. If you have a promising development opportunity, please contact us.

### Contact Information

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### ICAV in Action: Case Study

This case study presents a concrete example of the way in which ICAV bridges the commercialization gap. The subject is a scientist at a Canadian University and a member of ICAV's international network. He has developed groundbreaking technology for the discovery and generation of novel protein therapeutics as anti-virals and has turned to ICAV as a commercialization partner.

### ICAV Review and Licensing of Opportunity

- The Initial Review of Opportunity (IRO) assessed the scientific and medical prospects, intellectual property landscape, market needs and competition. This assessment included investigator input, both written and verbal.
- ICAV licenses promising candidates from the academic institution offering comparable licensing terms to any commercial entity, including upfront payment, milestones and a royalty stream.

### Supporting Translational Research

ICAV provides the necessary funding and expertise to complete the "translational research" required to convert the most promising academic opportunities into viable drug candidates.

ICAV provides:

- Direct financial support to the investigator's laboratory for continuing R&D work. In this example, annual direct financial support will total more than \$60,000.
- Access to critical specimens and reagents from ICAV's scientific network. In this case, ICAV is identifying and delivering crucial biomedical specimens from around the world to the investigator.
- Essential resources such as cell fermentation, protein purification and bioanalytical support that will enable generation of novel therapeutics at a scale suitable for experiments. In this case, ICAV is providing the fermentation and purification of a recombinant reagent crucial for the generation of novel anti-virals.
- Support for external contract research to provide *in vivo* proof-of-principle in animal models developed by ICAV network members.
- Experienced in-house legal expertise to guide the evolution of licensed IP for maximum value.

### Adding Value to Development Opportunities

Navigating an opportunity through the drug registration process can add substantial commercial value to stakeholders. The TRC offers expertise in all areas required for drug registration, including pre-clinical POC, process development, drug manufacturing & formulation, pharmacology & safety, QA/QC, clinical trial design, regulatory strategy, marketing potential, etc. ICAV provides guidance with the multiple regulatory agencies involved in the approval of new drugs for the world market (FDA, Health Canada, EMA, developing country agencies, etc.). ICAV actively seeks out commercial partners around the world for developed-country markets and partners for distribution in lower- and middle-income countries.