



The ICAV Solution

ICAV is an institutional innovation that bridges the anti-viral gap by connecting promising academic research directly to an experienced drug development team, providing the resources and knowledge 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.

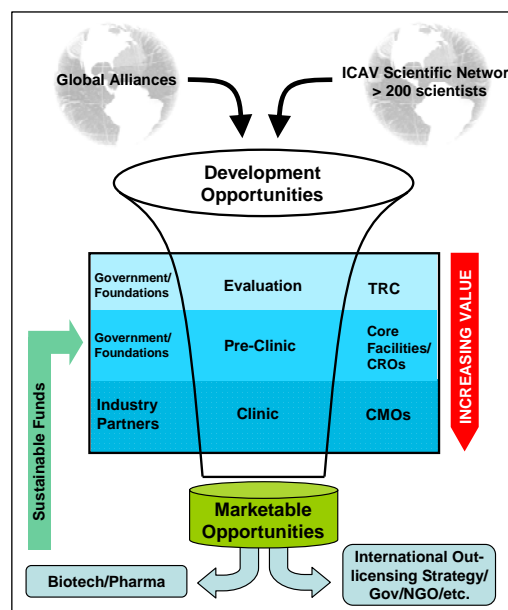
The centrepiece of the ICAV business model is the added value that ICAV creates by rapidly and cost-effectively moving anti-viral discoveries from research institutions into clinical trials. ICAV harvests promising drug candidates from academic scientists worldwide and moves them through the development pipeline.

An Innovative Drug Development Process

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 proof-of-concept (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 pre-clinical proof of efficacy, toxicology, pharmacology, formulation development and manufacturing, and clinical development. Resources are sourced along the way from CMOs, CROs, and the ICAV global scientific network.

Translational Research

ICAV provides the missing institutional link—coupling academic discoveries to industry and development expertise—that bridges the innovation gap between academic research and clinical development. This ‘virtual’ drug development model allows ICAV to leverage existing resources and comparative advantages, reducing the cost of the drug development process. ICAV’s public-private approach mitigates a great deal of the risk of drug development and encourages the realization of therapies for diseases that would otherwise be discounted by commercial drug companies. Through public and philanthropic support and cooperation with industry, ICAV will offer low-cost drugs to the developing world while meeting urgent health needs in the West.



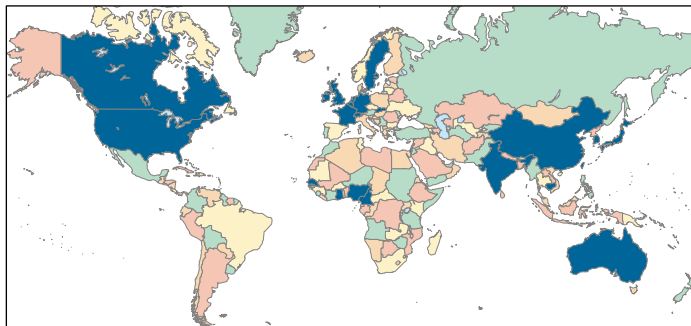
ICAV’s goal is the delivery of one new drug to market every five years.



International Consortium on Anti-Virals

Networking

Networking is an integral part of the ICAV business model. Through an ongoing series of international symposia, ICAV has developed a network of over 200 experts in all areas of anti-viral drug discovery. This broad-based network helps academics to harmonize their research with the needs of drug development by providing cross-disciplinary and industry expertise. ICAV's network also engenders cooperation by providing a forum to exchange important data and a mechanism to organize substantive collaborations.



The ICAV scientific network spans 24 countries and over 90 institutions.

Intellectual Property

ICAV follows standard practice in obtaining intellectual property from research institutions and out-licensing agreements with third parties. ICAV negotiates exclusive, sublicenses with commercial partners for markets in the developed world while retaining rights that ensure that products will be available to lower- and middle-income countries (LMIs) at affordable prices. Where commercial sublicenses are executed, institutions will benefit from royalties on sales by the commercial partner.

Governance

To ensure efficient, effective and accountable administration of ICAV's drug pipeline, ICAV utilizes a private-sector management structure including an independent Board of Directors and external audits. Compounds approved for development by the TRC are assigned a professional manager who supervises the clinical development of the compound. Scientific direction emanates from the International Research Advisory Board (IRAB), composed of internationally recognized scientists. The International Steering Committee provides international governance advice.

Scientific Platform

ICAV is developing "wide-spectrum" anti-viral drugs that will target a variety of viral diseases while avoiding the emergence of resistant viruses. The ICAV scientific platform fundamentally changes the playing field by deploying a novel array of innovative "blocking" strategies that target human cell functions essential to viral infection. Because of their rapid mutation rate, many viruses are able to develop resistance to conventional anti-virals that target virally encoded functions. The power of ICAV's strategy lies in the fact that human functions do not mutate. Furthermore, as many viruses use the same set of human cellular functions, drugs that inhibit these functions in the cell have the potential to work against a wide range of existing and newly emerging viruses.



International Consortium on Anti-Virals

Cheaper Drugs

ICAV estimates that it can produce drugs at less than 20% of the cost of traditional pharmaceutical approaches.

- ICAV leverages billions of dollars spent each year by national governments on basic research.
- ICAV licenses compounds after initial proof-of-concept, reducing risk of failure by 10.
- Public and philanthropic funding of pre-clinical development further reduces risk.
- Use of international scientific network throughout drug development pathway reduces personnel and infrastructure costs.

Conclusion

ICAV represents an institutional innovation that fills an urgent need: Anti-viral drugs that are readily available, affordable around the world, and resistant to viral mutations. An integral part of a holistic approach to public health, novel anti-virals will offer cost-effective treatments for existing viral diseases while providing a bulwark against future pandemics. The provision of new, cost-effective anti-virals is also integral to the realization of the Millennium Development Goals; without a new model for drug-development, infectious diseases will continue to hinder the development aspirations of low and middle income countries.

ICAV will deliver on this goal not by competing with existing structures but by facilitating partnerships and taking advantage of the unique demands and opportunities of the global drug development market. By harnessing a grassroots network of scientists and institutions and a global discovery pipeline and coupling it with a professional drug development expertise and a unique IP strategy, ICAV will be able to ensure the efficient and affordable development of new anti-virals.



Corporate Profile

ICAV/CITAV was incorporated in January 2006 as a company without share capital under part II of the Canada Corporations Act (file number 433450-7) and operates as a not-for-profit drug discovery and development company. The CCRA Business number is 81327 9478.

Offices: The head office of ICAV is located at Trent University, Peterborough, Ontario. ICAV also maintains an International Partnership office located within the Ottawa Health Research Institute in the city of Ottawa, Canada's capital. ICAV's Africa Regional Office is located at the University of Ibadan, Nigeria, under the direction of Dr. Oyekanmi Nash.

Directors: Jeremy Carver, Michel Chrétien, Philippe Douste-Blazy, Brian Gray, Patrick Michaud (Chair), Bonnie M. Patterson.

Special Advisor to the CEO: Hon. Donald Johnston.

International Research Advisory Board: Sir John Skehel (Chair), Peter Doherty, Donald Low, Jeremy Carver, Michel Chrétien, Nabil Seidah.

Management Team: Jeremy Carver, President, CEO & CSO; Michel Chrétien, International Partnerships; Dale Cumming, Director of Scientific Evaluation; Denis Ferkany, Director of Corporate Strategy; Wendy Hill, Director of Clinical Development; Linda Kurdydyk, Director of Intellectual Property; Nathaniel Lewis, International Partnerships & Communications; Regional Director, Africa, Dr. Oyekanmi Nash.

International Steering Committee: Dr. Ralf Altmeyer, CEO, CombinatoRx, Singapore; Dr. Jeremy Carver, CEO, ICAV, Canada; Dr. Michel Chrétien, International Partnerships, ICAV, Canada; Dr. Erik de Clercq, Faculty of Medicine, Rega Institute, Leuven, Belgium; Dr. George Fu Gao, Institute of Microbiology, CAS, Beijing, China; Dr. Rolf Hilgenfeld, Director, Institute of Biochemistry, University of Lübeck, Germany; Dr. Hans-Dieter Klenk, Institute of Virology, University of Marburg, Germany; Dr. Albert Osterhaus, Head, Department of Virology, Erasmus University, Netherlands; Sir John Skehel, Former Director of the MRC-NIMR, Mill Hill, UK; Professor Oyewale Tomori, Vice Chancellor, Redeemer's University, Nigeria; Dr. Noël Tordo, Institut Pasteur, France; Dr. Igor Tvaroska, Director, Institute of Chemistry, Slovak Academy of Sciences, Slovakia; Dr. Mark von Itzstein, Director of the Institute for Glycomics, Griffith University, Australia; Dr. Andrew Wang, Director, Institute of Biological Chemistry, Academia Sinica, Taiwan.

Technical Review Committee: Theo Anucha, Formulation and Manufacturing; Isobel Ralston, Pre-clinical Development; Miklos Shultz, Clinical Design and Biostatistics; Saul Ship, Market Analysis; Anne Tomalin, Regulatory Affairs.