



*Protecting your discoveries, advancing  
the stage of development and creating  
products for the public benefit:  
the role of TIDO*

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*Director of Technology and Business Development*





## TIDO Mission

*“to translate the laboratory and clinical research excellence and innovations at Children's Hospital Boston (CHB) into products for the public benefit”*





# Children's Policy on Inventions and Intellectual Property

## **Policy Aims:**

- Promote commercial development of the Hospital's research and clinical discoveries
- Encourage inventorship through financial rewards
- Build the Hospital's research endowment

## **Ownership and Distribution of Intellectual Property:**

- The Hospital owns all IP developed by any person on the premises of the Hospital, or through substantial use of the Hospital's resources or facilities.
- Policy does not inhibit the free communication of ideas and research results through teaching, research collaboration and publication; however, inventors are encouraged to disclose their findings to TIDO prior to any such communications.

## **Disclosure of Inventions:**

- Communicated to TIDO via Invention Disclosure Form
- An invention is a novel, non-obvious and useful idea relating to processes, machines, manufactures and compositions of matter





## The Steps:

- Disclose technology
  - investigators disclosure to TIDO
- Evaluate technology
- Protect technology
  - via patents, copyright, trademark or trade secret
- Develop technology
- Market technology
- Negotiate licenses
- Manage licenses





# Bayh-Dole Act (1980)

- to encourage economic development and improve U.S. industry competitiveness by allowing universities to retain title to inventions arising from federally funded research
  - *Increase efficiency of commercialization of innovations*
- Allows universities to license inventions and receive royalties
- Requires “substantial U.S. manufacture” and that portion of royalties be paid directly to inventors





## Why does CHB seek patent protection?

- To bring CHB inventions and discoveries into public use as rapidly as possible while protecting academic freedom
- We use patenting and licensing to encourage development of CHB inventions by industry
- Prospective licensee's need to secure IP protection and “exclusivity” that will protect the capital investment in early stage technologies





# What is a Patent?

- “...the right to exclude others from making, using, offering for sale, or selling the invention.”  
(35U.S.C.§154)
- **A common misconception:** A patent does not grant permission to the inventor or his or her assignee to make use or sell his or her invention it is....
- A right granted for the owner to prohibit others from....making, using, or selling the invention, offering the invention for sale and even importing the invention.





# What is a patentable invention?

- **Invention:** *“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor...”*  
**(35U.S.C.§101)**
- **New and Useful (35U.S.C.§101)**
- **Novelty and Prior Art (35U.S.C.§102)**
- **Non-obvious (35U.S.C.§103)**
- **Enablement and Best Mode (35U.S.C.§112)**





**... can result in loss of patent rights**

*Examples*

1. Manuscripts
2. Abstracts
3. Seminars
4. Company Presentations
5. Dissertations
6. Grant application upon award (through FOI)





# Who is an inventor?

- **Inventor:** *“...a person who alone or in conjunction with others discovers an invention.”*
- Conception is the touchstone to determining inventorship
  - *“definite and permanent idea of the complete and operative invention. . .such that it would enable a person of ordinary skill in the art to convert the idea to tangible form without extensive research.”*





# Licensing Results

- From licensing...
  - **10** medical products on the market
  - **6** products in clinical trials
  - **30** products for future clinical testing
  - **140** other licensed technologies
- More than **23** new companies have been started around Children's Hospital technologies














# CHB products in clinical development

<i>Name</i>	<i>Company</i>	<i>Phase 1</i>	<i>Phase 2</i>	<i>Phase 3</i>	<i>NDA</i>
Revlimid (various cancer indications)	Celgene	Phase 1	Phase 2	Phase 3	
Tissue engineered bladder	Tengion	Phase 1	Phase 2		
Panzem (Rheumatoid Arthritis)	EntreMed	Phase 1	Phase 2		
D-Penicillamine (lead poisoning - pediatric)	Bezoloven	Phase 1			
Neuropilin (Solid Tumors)	Genentech	Phase 1			
Von Willebrand Factor (Hemophilia A)	Baxter	Phase 1			





# Products on the Market

<i>Product</i>	<i>Description</i>	<i>Company</i>
	angiogenesis inhibitor for the treatment of multiple myeloma	
	angiogenesis inhibitor for the treatment of multiple myeloma	
CardioSeal and StarFlex	devices to close different types of holes in the heart	<b>NMT Medical</b> BRINGING CLOSURE TO CARDIAC SOURCES OF STROKE™
	NMDA-receptor antagonist for the treatment of Alzheimer's disease	 
Neumega	synthetic IL-11 to prevent low platelet counts caused by chemotherapy	<b>Wyeth</b>
Dystrophin Test	diagnostic test for Duchenne muscular dystrophy	
EchoIMS	echocardiography image and information management system for fetal, neonatal and pediatric indications	
QuickChange Mutagenesis Kits	The mutagenesis kit --3 easy steps to introduce a variety of mutations in any vector in a single day.	<b>STRATAGENE</b> An Agilent Technologies Company





# Inventors Share of Licensing Revenue

## Distributions of proceeds while Inventor is a Children's Hospital Boston employee

Cumulative Net Lifetime Revenues	Inventor	Inventor's Department	General Research Endowment	Technology & Innovation Development Office
Up to \$100K	70%	0%	20%	10%
\$100K-\$500K	45%	20%	25%	10%
Above \$500K	25%	25%	40%	10%

Note:

- There may be several inventors
- Patenting & out-of-pocket expenses are deducted first before distribution of income





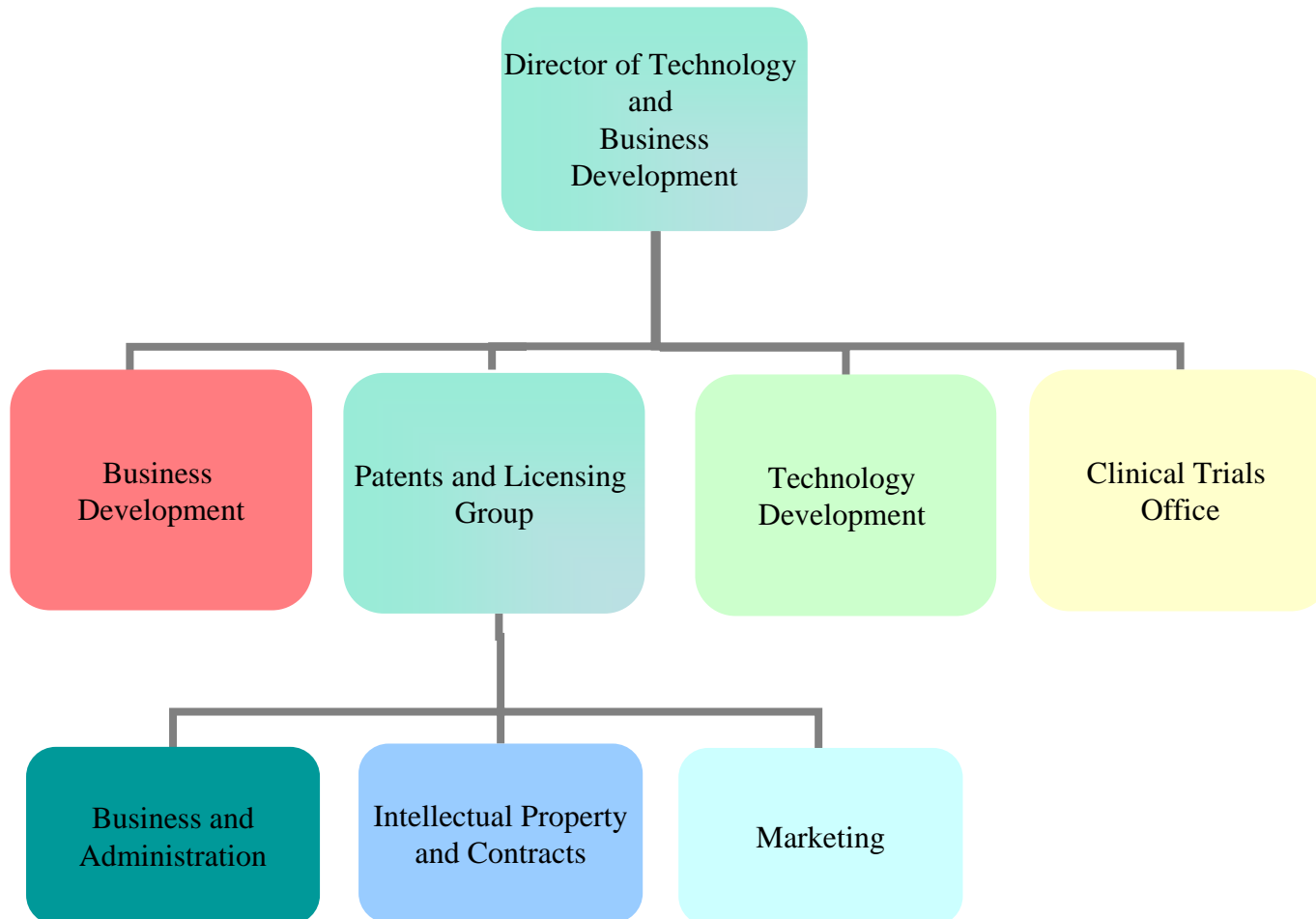
# What can TIDO do for you?

- Evaluate, protect and manage intellectual property (P&L)
- Advise on industry relations and help establish collaborations (Bus Dev)
- Market and license technologies (P&L)
- Develop technologies (Tech Dev)
- Facilitate company startups
- Negotiate industry agreements
  - *Material Transfer Agreements (MTAs)*
  - *Sponsored Research Agreements*
  - *Clinical Trial Agreements*



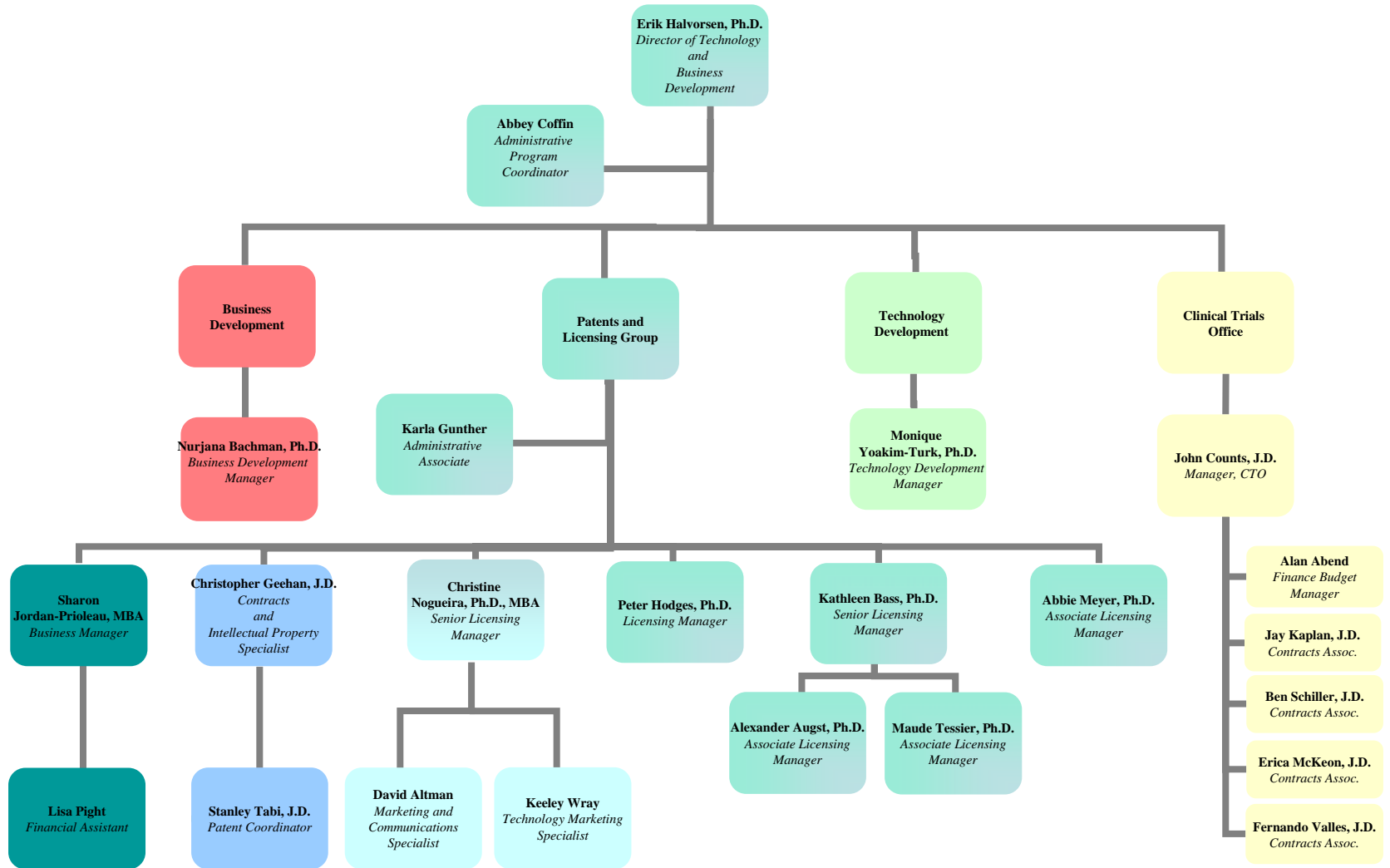


# TIDO Functional Org Chart





# TIDO Personnel Org Chart





## Business Development @ TIDO

“The Business Development group within TIDO connects Children’s Hospital Boston investigators with outside industry to **create opportunities for partnerships at all stages of research, development, and pre-clinical and clinical investigation.**”





# Business Development Activities

The Business Development group:

- **Generates profiles of research and researchers** at Children's Hospital that outline recent and ongoing work, future goals and potential areas of collaboration with industry.
- **Proactively meets with** biotechnology, pharmaceutical, device, informatics and diagnostic **companies** to understand their R&D areas of interest and goals.
- **Provides preliminary information** reciprocally to Children's Hospital researchers and corporate parties enabling further evaluation for a potential collaboration.
- **Coordinates scientific meetings for companies** with individual/multiple investigators or entire departments for both sides to explore collaborative projects.



# TECHNOLOGY DEVELOPMENT FUND

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## **Problem:**

“*Gap*” between early stage of development of technologies/innovations arising from CHB and the preferred later stage opportunities sought by industry

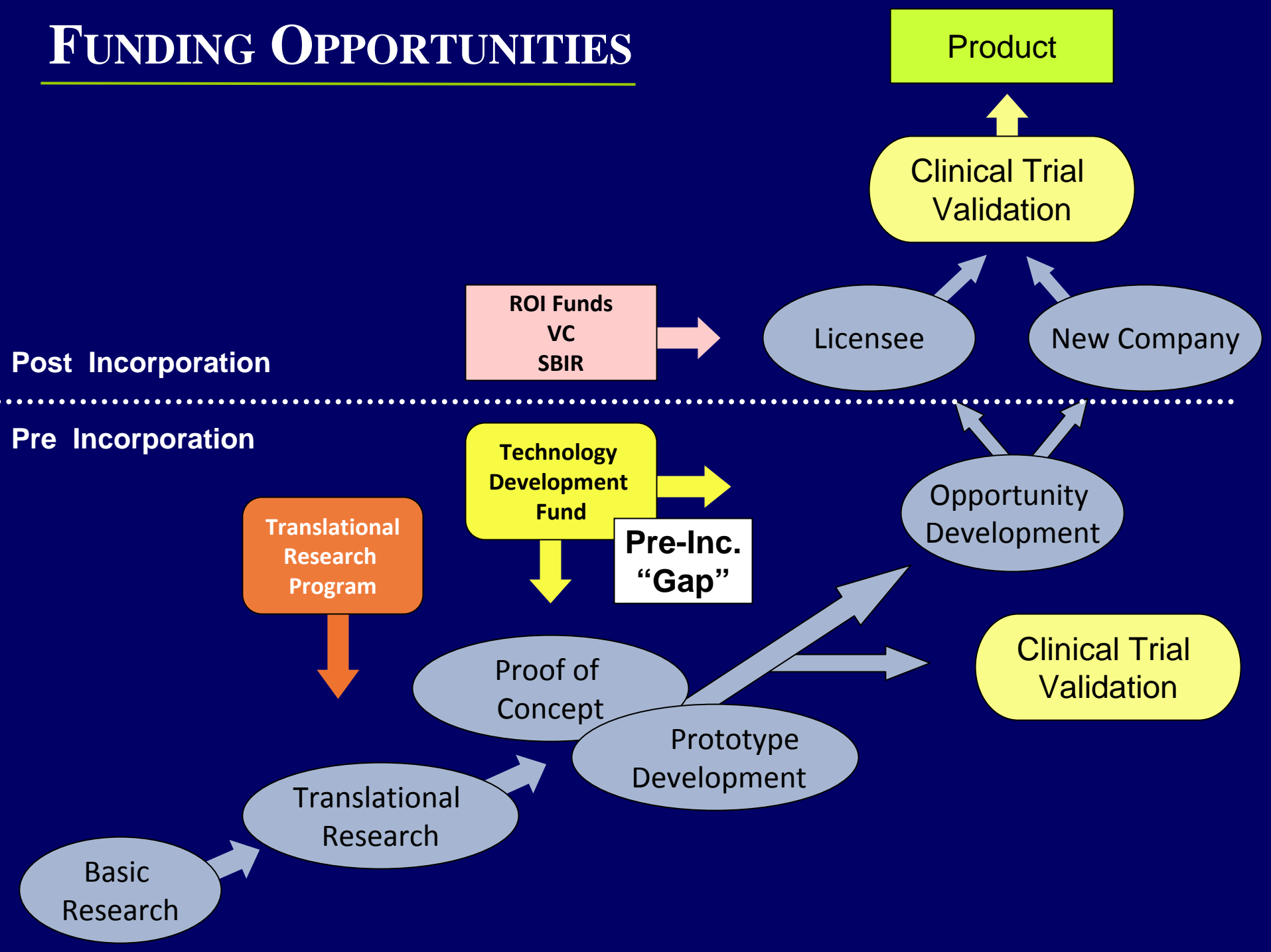
## **Solution:**

To apply a multifaceted approach to advance promising CHB technologies/innovations and increase the probability of products being developed for public benefit

## **Approach:**

- Funds
- External advisory board of Industry experts
- Product development and technical support
- Project management and CROs

# FUNDING OPPORTUNITIES



# TECHNOLOGY DEVELOPMENT FUND

Stages of  
Development

Early

Late



	<b>Proof of Concept Grant</b> <b>&lt;\$50,000</b>	<b>Technology Commercialization Grant</b> <b>&lt; \$250,000</b>
	Moves Technology	Market Identified Technology Demonstrated
Characteristics	<ul style="list-style-type: none"> <li>▪ IP landscape and market assessment completed</li> <li>▪ Helps licensing or attract additional funding</li> <li>▪ Prototype creation</li> <li>▪ Hit/Target validation</li> <li>▪ Annual/ project management</li> </ul>	<ul style="list-style-type: none"> <li>▪ Already validated concept</li> <li>▪ Clear patent strategy and defined commercialization path</li> <li>▪ Expands portfolio/Adds value</li> <li>▪ Substantial preclinical package</li> <li>▪ Return on Investment</li> <li>▪ Annual/project management</li> </ul>



# FUND ADVISORY BOARD

<u>Advisor</u>	<u>Title</u>	<u>Company</u>
Dean Banks, MBA	CEO	Connective Orthopedics
Alan Crane, MBA	Venture Partner	Polaris Venture Partners
Russ Granzow	VP Strategic Business Dev	Philips
Stanley N. Lapidus, BSEE	Director/Founder/Chairman of the Board	Helicos Biosciences Corp
Larry Miller, MD	Founding Partner	Mediphase Funds
Stuart Pollard, PhD	VP Scientific and Business Strategy	Alnylam
Ken Rhodes, PhD	VP Discovery Neurobiology	Biogen Idec
Jay Schnitzer, MD, PhD	Associate Chief Medical Officer, VP	Boston Scientific Corp
Joseph Smith, MD, PhD, FACC	VP Emerging Technologies	J&J
Beverly Teicher, PhD	VP Oncology Research	Genzyme Corp
Josh Tolkoff, MS Eng	Managing Director	Ironwood Capital Management, LLC
Daphne Zohar	Founder, Managing Partner	PureTech Ventures





# Who We Are

**Erik Halvorsen, Ph.D.**  
Director of Technology and  
Business Development

**Patents and Licensing Group**

Christine Nogueira, Ph.D., MBA

Kathleen Bass, Ph.D.

Peter Hodges, Ph.D.

Abbie Meyer, Ph.D.

Christopher Geehan, J.D.

Maude Tessier, Ph.D.

Alexander Augst, Ph.D.

David Altman

Keeley Wray

Stanley Tabi, J.D.

**Technology Development**

Monique Yoakim-Turk, Ph.D.

**Business Development**

Nurjana Bachman, Ph.D.

**Deputy General Counsel**

Patrick Taylor, Esq.

**Clinical Trials Office**

John Counts, J.D.

Jay Kaplan, J.D.

Alan Abend

Benjamin Schiller, J.D.

Erica McKeon, J.D.

Fernando Valles, J.D.

**Business and Administration Group**

Sharon Jordan-Prioleau, MBA

Lisa Pight

Abbey Coffin

Karla Gunther





# Case Manager Dept/Div/Program Assignments

## **Alex Augst**

- Anesthesiology
- Cardiac Surgery
- Dentistry
- Orthopedic Surgery
- Plastic & Oral Surgery
- Psychiatry
- Radiology

## **Nurjana Bachman**

- Adolescent & Young Adult Medicine
- Nursing/Patient Care Operations
- Surgery
- Vascular Biology Program

## **Kathleen Bass**

- Cardiology
- Developmental Medicine
- Endocrinology
- Newborn Medicine
- Ophthalmology
- Otolaryngology
- Pharmacy

## **Peter Hodges**

- Genetics
- Genomics Program
- Informatics Program
- Molecular Medicine
- Proteomics
- Stem Cell Program

## **Abbie Meyer**

- GI/Nutrition
- Hematology/Oncology
- Immunology
- Infectious Disease
- Rheumatology

## **Christine Nogueira**

- Dermatology
- Emergency Medicine
- General Pediatrics
- Gynecology
- Laboratory Medicine
- Neurobiology Program
- Neurology
- Neurosurgery
- Pathology

## **Maude Tessier**

- Nephrology
- Respiratory Diseases
- Urology
- Vascular Biology Program





Questions?

## ***Give us a call!***

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- Website: [www.childrensinnovations.org](http://www.childrensinnovations.org)





# TIDO Location



**120 Brookline Ave.  
(One block from Fenway Park)**

