

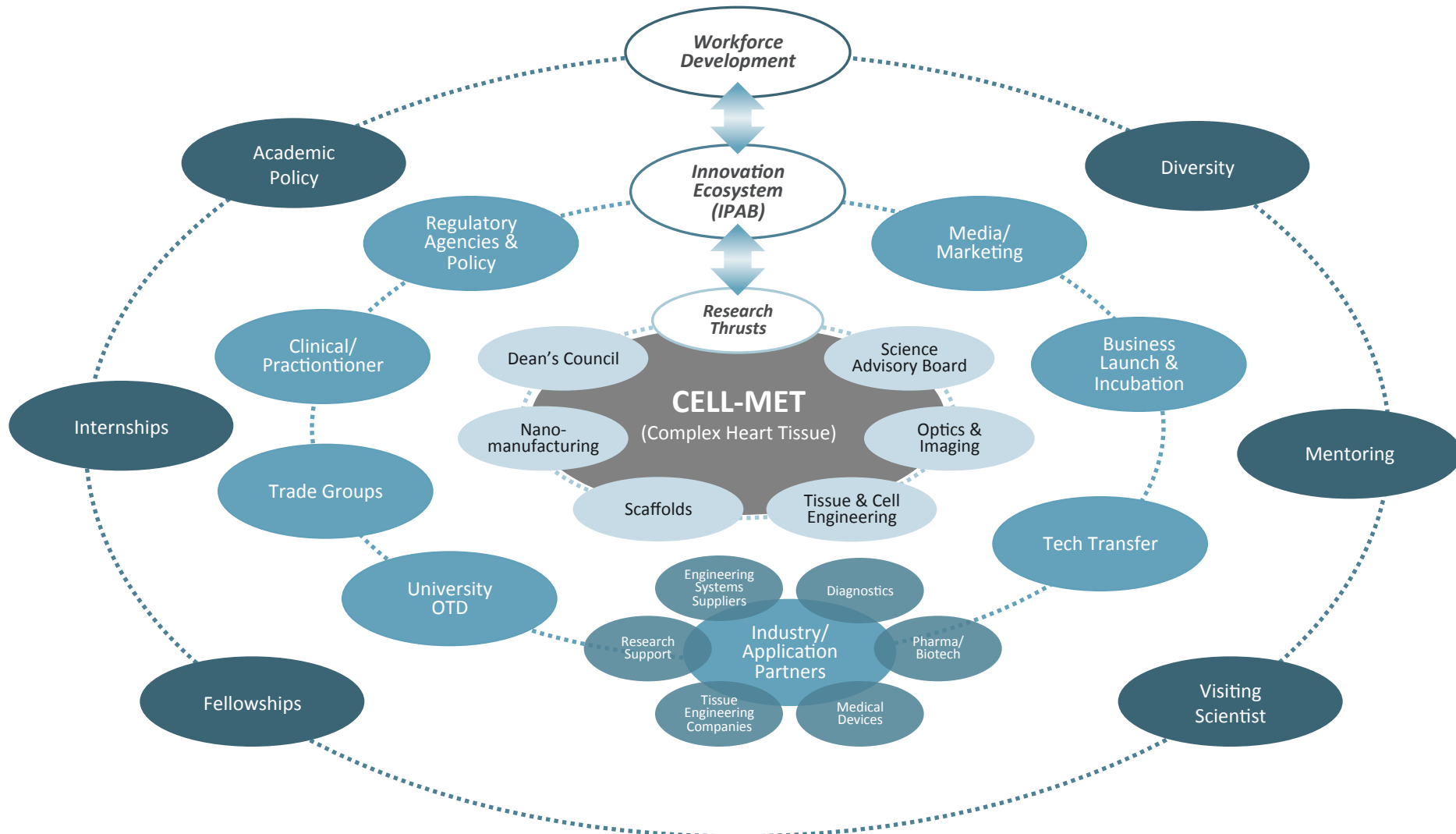
Innovation Ecosystem

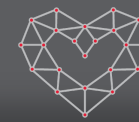
Thomas Dudley

Asst. Director, BUPC

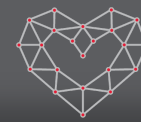


CELL-MET





- Academic Members
 - Core Academic Members (BU, UM, FIU)
 - Multiple researchers, contribute cost share, significant contribution to education and outreach.
 - Member Council of Deans.
 - New core academic members by invitation of Deans.
 - Non-Core Academic Members
 - Provide crucial technology expertise, may offer educational programs and industry networks.
 - New non-core academic members by invitation of Director.
- Industry Members
 - Open to all for-profit or non-profit corporations, foundations, government agencies, federally funded research & development corporations (FFRDC) and government owned contractor-operated laboratories.
 - Four classes of membership:
 - Sustaining, Full, Associate, Affiliate



- More focused on Industry interest over next 3 years vs. the centimeter scale multi-functional cardiac tissue
- Should involve more biofabrication companies



MEMBERSHIP OUTLOOK – SITE VISIT

Engr. System Suppliers



Tissue Engineering



Research Tool Suppliers



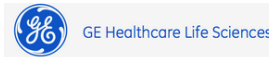
Engineered System Support



Pharma/Biopharm



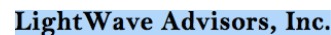
Diagnostics



Implant/Medical Devices



Other





MEMBERSHIP OUTLOOK – SITE VISIT

Engr. System Suppliers



NOKIA Bell Labs



Tissue Engineering



Research Tool Suppliers

“Any one of these companies is not the solution, it is all of them working together”

Engineered System Support

Pharma/Biopharm

Diagnostics

Implant/Medical Devices

Other

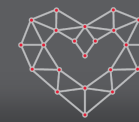


Hale Ventures, LLC

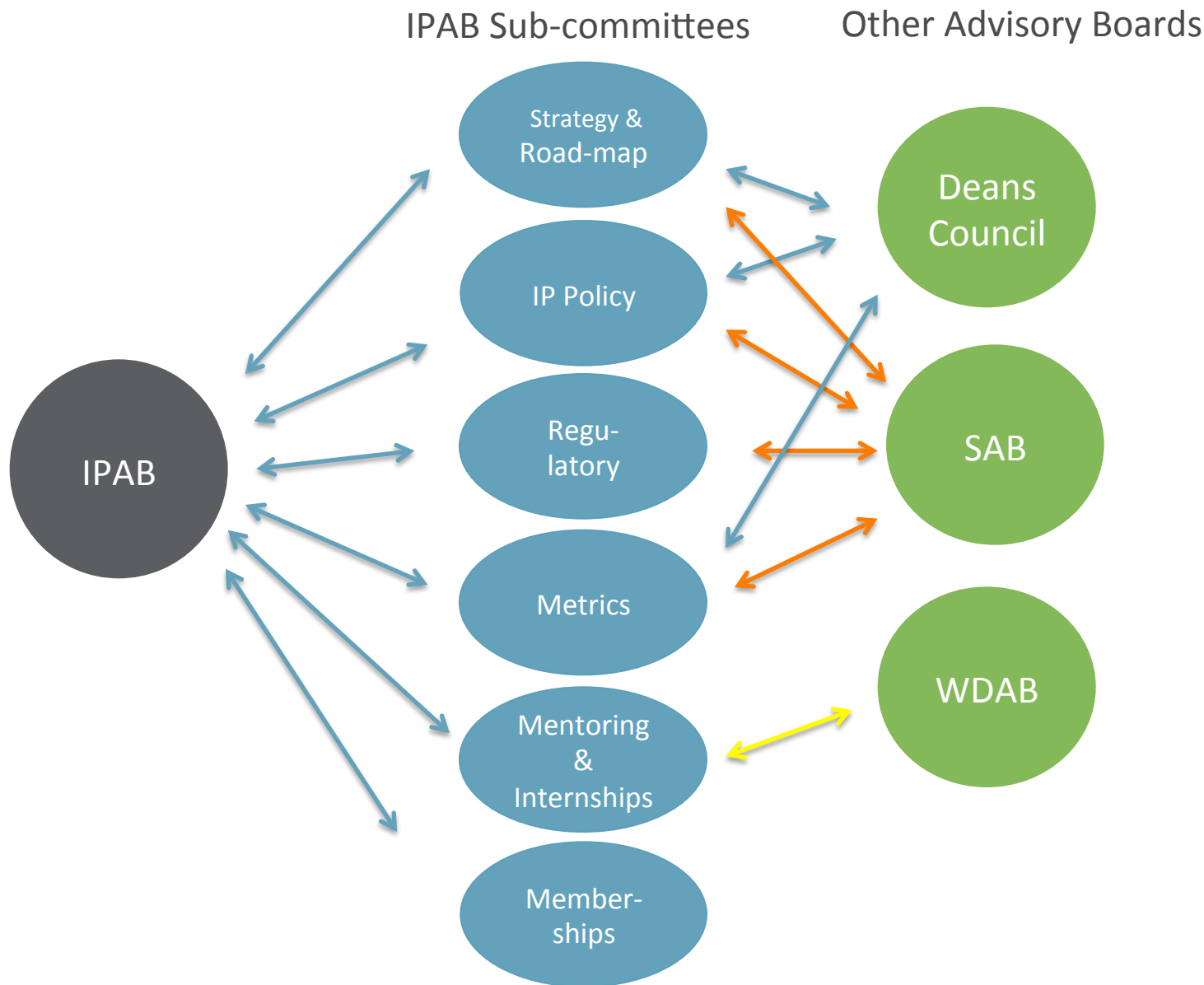


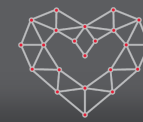
LightWave Advisors, Inc.





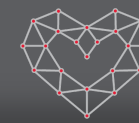
- Mechanism for Industry Input.
 - Chair/Vice-Chair of IPAB on Senior Leadership Team.
 - Visiting Scientist program.
 - Industry Exhibition at Annual Retreat.
 - Recommend Seed projects.
 - Advise on use of membership fees:
 - Fellowships
 - Internships
 - Seed projects
 - IP Protection Fund
 - Allocation for core research
 - IPAB Sub-committees:
 - Have an involved and committed sub-group of IPAB members to address topics such as IP, Mentoring, Internships, etc.





- Plan for engagement with FDA/regulatory agency
 - Not immediately required.
 - Will seek advice from experienced members of IPAB.
 - Will recruit good regulatory consultants to join IPAB.
 - Form IPAB sub-committee to address:
 - Communication strategy with FDA.
 - How early in product development lifecycle to engage FDA?
 - How to prepare for engagement with FDA?
 - Treat FDA as a CELL-MET partner and invite as IPAB member at appropriate time.

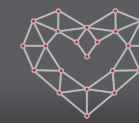
IPAB Membership Structure



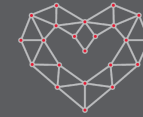
	SUSTAINING	FULL	ASSOCIATE	AFFILIATE
Membership Fee	\$100K	\$25K	\$1K	“In-kind”
IPAB Seat	1 per membership, Observer(s)	1 per membership, Observer(s)	1 per member	No
IPAB Chair	Yes	No	No	No
Sub-Committee Participant	Yes	Yes	Yes	Yes
Sub-Committee Chair	Yes	Yes	Yes	Yes
Voting	1 seat = 10 vote	1 seat = 3 votes	None (can influence vote)	None (can influence vote)
# Voting Memberships	Up to 3	Up to 3	1	1
Option for Scientist in Residence	Yes	Yes	No	No
Option for Project Research	Yes	Yes	No	No



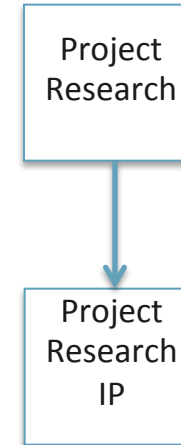
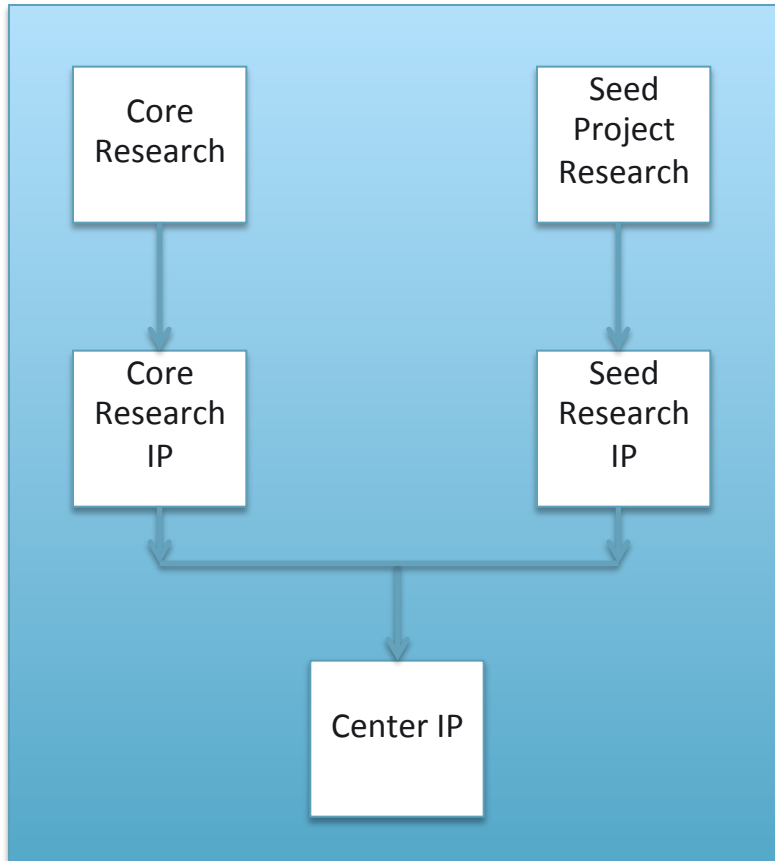
	SUSTAINING	FULL	ASSOCIATE	AFFILIATE
Member IP Rights:				
Review Research Make Rcmd.	Yes	Yes	Yes	Yes
Advise on IP protection	Yes	Yes	Yes	Yes
NERF for non- commercial internal research use only	Yes	Yes	Yes	Yes
Royalty bearing commercial license	1 st Option	2 nd Option	2 nd Option	Open Option Period

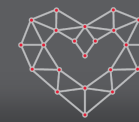


	SUSTAINING	FULL	ASSOCIATE	AFFILIATE
Other Benefits:				
Facilitated access to students & faculty	Yes	Yes	Yes	Yes
Pre-publication research access	Yes	Yes	Yes	Yes
Acknowledgement in Manuscripts	Yes	Yes	Yes	Yes
Opportunity for joint authorship	Yes	Yes	Yes	Yes
Participation in Center networking events & meetings	Yes	Yes	Yes	Yes



- Membership Agreement
- Center Bylaws
 - IP Policy incorporated in bylaws
 - Defines membership categories, fees, benefits, responsibilities.
 - Addresses center organization and leadership
- Documents reviewed by Elysium Holdings, ready for NSF review and approval





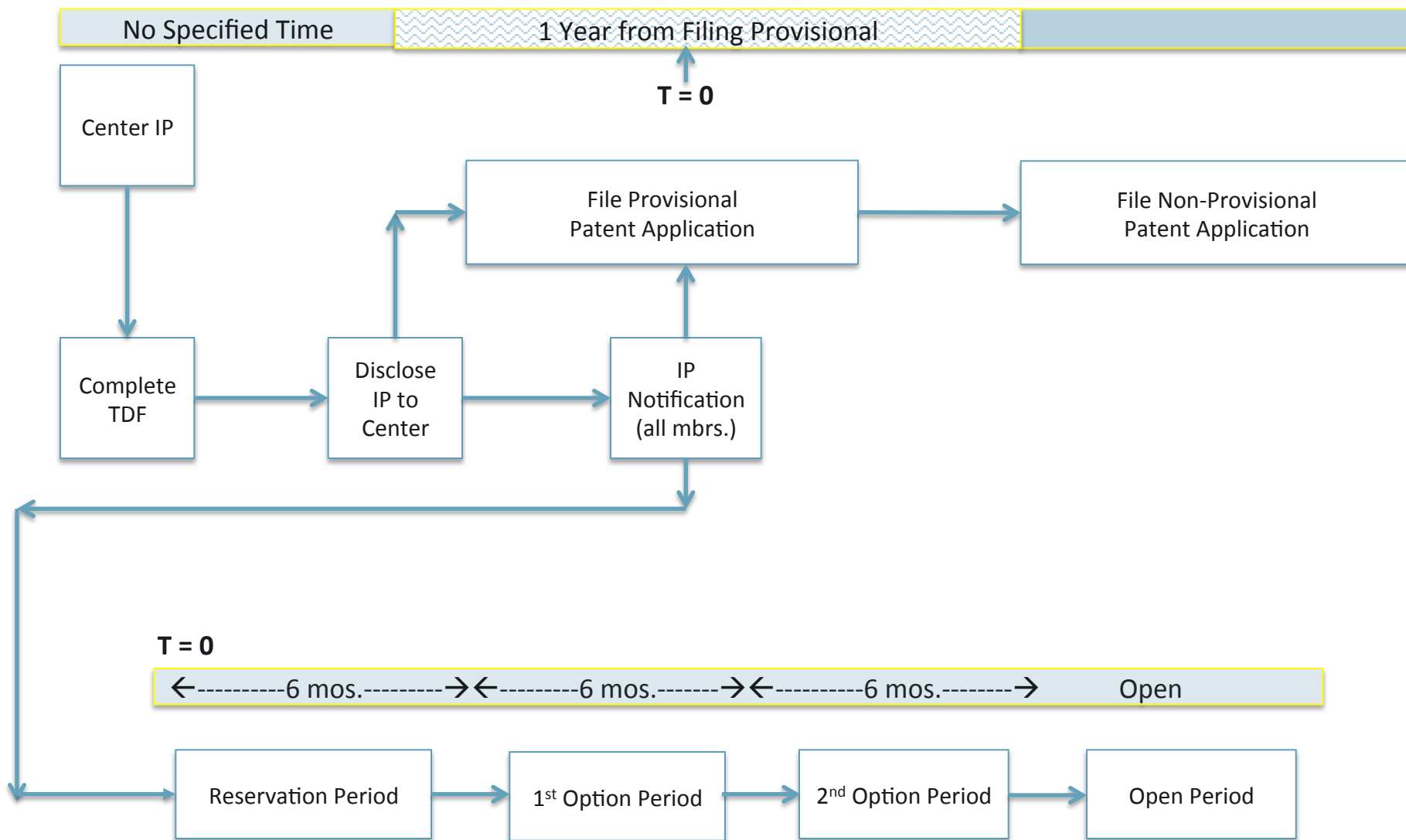
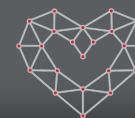
Environmental Factors:

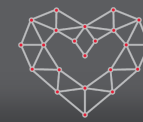
- Risk of Overhanging Market with pre-mature technology.
- Long Adoption Cycles.
- High costs and risks associated with FDA approvals.

Considerations on IP Management:

- Exclusive licenses available, but not a member right → Needs to be earned & demonstrate how technology will move forward.
- Two tier licensing model to Member companies.
 - Require membership at time of invention disclosure.
- New company launches are encouraged.
 - To exploit CELL-MET innovations new company creation window authorized during reservation period.
- Pair IP protection with overseas FDA approvals

Commercial License Flowchart



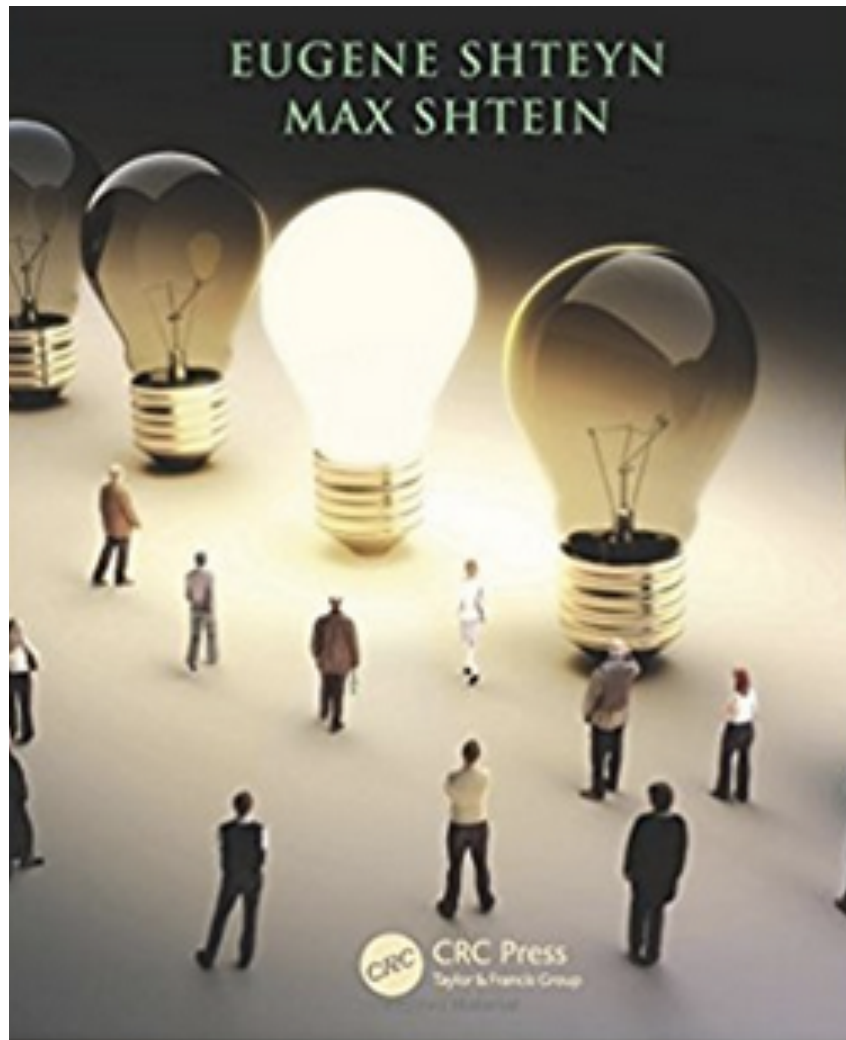
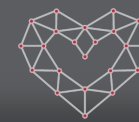


- Engineering Skills:

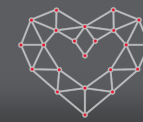
<ul style="list-style-type: none">• Nanofabrication	<ul style="list-style-type: none">• Controls/process automation
<ul style="list-style-type: none">• Wet lab experience	<ul style="list-style-type: none">• Optical microscopy and characterization
<ul style="list-style-type: none">• Process modeling	<ul style="list-style-type: none">• Mechanical analysis (statics & dynamics)
<ul style="list-style-type: none">• Circuit theory	<ul style="list-style-type: none">• Microfluidics
<ul style="list-style-type: none">• Multi-scale/multi-physics modeling of complex issues	

- Other Skills:

- General research ethics on issues specific to biotechnology & medical research
- Entrepreneurial mindset to drive innovation



- Framework for Encouraging/Executing New Company Launches:
 - Easy to join IPAB.
 - “Equality” in licensing opportunities.
 - Invitation to VC’s for membership in IPAB.
 - Allocation of business incubator space for start-ups supporting or spun out of CELL-MET research.
 - Collaboration with ARMI/BioFab USA
 - Workforce development plan to include existing Entrepreneurship programs and new on-line modules on Entrepreneurship.

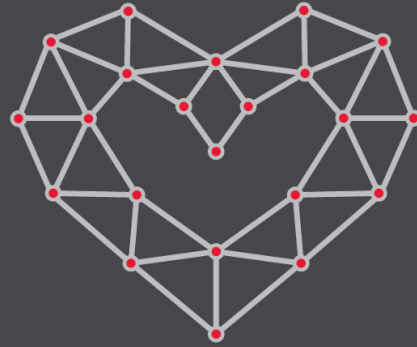


Moderator:

- Thomas Dudley – CELL-MET Industry Liaison Officer

Panelist:

- *David Bishop* – Director CELL-MET
- *Brendan Brinkman* – Senior Marketing Manager, Olympus America, Inc.
- *Gray Chynoweth* – Chief Membership Officer, ARMI, BioFab USA
- *John Taranto* – Senior Scientist, Advanced Systems Technology, Thorlabs
- *Chris Wilson* – Senior Scientist, Bioventus Surgical



CELL-MET

Questions

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