



GTMI

## External Advisory Board Meeting

NOVEMBER 12, 2014

**TABLE OF CONTENTS**

Agenda.....	page 3
External Advisory Board Biographies.....	pages 4-8
Georgia Tech Faculty Biographies.....	pages 9-13
Strategic Planning Report.....	pages 14-22
Overview of Alpha Test Approach.....	pages 23-26
Alpha Test 1.....	pages 27-33
Alpha Test 2.....	pages 34-36
Alpha Test 3.....	pages 37-42
Alpha Test 4.....	pages 43-51
Discussion and Feedback.....	page 52

**AGENDA****Wednesday, November 12, 2014**

<b>Time</b>	<b>GTMI EAB Agenda Timeline and Topics</b>	<b>Lead</b>
8:00	<b>Continental Breakfast</b>	
8:30	<b>Welcome and Meeting Expectations</b>	Steve Cross (GT EVPR) Theresa Kotanchek
8:45	<b>Strategic Planning Committee (SPC) Report</b>  - GT Vision, Strategy, and Organization Structure (Input from GT) - GTMI Vision, Mission, Strategy, and Operating Approach	Steve Cross (GT EVPR) SPC
9:30	<b>EAB Feedback on GTMI Strategy and Execution</b>	EAB
9:45	<b>Overview of Alpha Test Approach and Expectations</b>	McGrath & Kessler
10:00	<b>Morning Break</b>	
10:15	<b>Alpha Test of the GTMI Operating Approach</b>  1. Accelerated Innovation and Insertion of Advanced Composites 2. Trends in Logistics and Supply Networks	McGrath & Kessler  Chuck Zhang  Jennifer Clark, Soumen Ghosh & Chip White
	<b>Working Lunch</b>	
	3. Innovation In Incubators and Beyond for Achieving Maturation 4. Cell Bio-Manufacturing Technologies and Standards	Chris Downing  Krish Roy
1:45	<b>Discussion and Feedback on EAB Roles and Next Steps</b>  1. Is GTMI on the right track for GTMI strategy and execution? 2. Has GTMI captured the roles and skills scope of the EAB going forward? 3. EAB perspectives on formalizing a GTMI-EAB-IAB methodology identifying GTMI Manufacturing Challenges and entire "Engage Partners process"? 4. EAB proposed topics for the Spring 2015 EAB?	Theresa Kotanchek & EAB
2:45	<b>Adjourn</b>	Ben Wang

## EXTERNAL ADVISORY BOARD



Dr. Wayne Eckerle  
Vice President of  
Corporate Research and  
Technology, Cummins Inc.  
Columbus, IN

Wayne received a BS (1975) and MS (1976) in Aeronautical Engineering from Purdue University and a PhD in Fluid Mechanics from the University of Connecticut in 1985. Prior to joining Cummins, Wayne worked at UTRC for 10 years on a variety of internal flow projects including chemical laser systems, scramjets, and gas turbine combustion. Wayne was also an Associate Professor at Clarkson University teaching classes in Thermal Sciences and performing research in turbulent separated flows, two-phase flow heat transfer, and supersonic combustion.

Since joining Cummins in 1989 Wayne has held leadership positions in Metrology, Quality, Fuel Systems Technology, Thermal and Fluid Sciences, and Advanced Engineering. In his present position, Wayne is responsible for developing and integrating technology for Cummins' next generation of products. Wayne received the Cummins J. Irwin Miller Award of Excellence in 2005, an Honorary Doctorate from Purdue University in 2009, the Cummins Julius Perr Innovation Award in 2009, and became an SAE Fellow in 2011.



Dr. Bill Kessler  
Palisades Enterprises  
LLC

Dr. Bill Kessler is the Director of Executive Programs in the Tennenbaum Institute and a Professor-of-Practice in the School of Industrial and Systems Engineering. His focus is on large scale enterprise transformation and specifically on aligning multi-disciplinary research with real world transformation needs such as capabilities for network centric manufacturing and logistics.

Previously, he was Lockheed Martin Aeronautics Vice President for Enterprise Initiatives. Among his accomplishments were leadership roles in deploying six sigma quality and lean principles across the company and, beginning in early 2000, being the executive architect for the leadership team that accomplished the successful restructure and transformation of Lockheed Martin's three aeronautics companies into one company, LM Aeronautics.

Kessler has served as a senior executive with the United States Air Force. In the position of Director of Manufacturing Technology and Industrial Base Analysis, he led many pioneering initiatives, including the creation of the Lean Aerospace Initiative (LAI) a partnership among government, industry, academia, labor to address the affordability of military aerospace systems. Dr. Kessler holds a B.S. and M.S. in Aeronautical and Engineering Sciences from Purdue University and a Doctorate in Chemical Engineering from Washington University in St. Louis, Mo. He spent a year studying fluid mechanics at the von Karman Institute in Brussels, Belgium and has attended the Harvard School of Government, the Federal Executive Institute and the Lockheed Martin Executive Learning Institute.

## EXTERNAL ADVISORY BOARD



Dr. Theresa Kotanchek  
Chief Executive Officer  
and co-founder of Evolved  
Analytics LLC

Dr. Theresa Kotanchek is the Chief Executive Officer and co-founder of Evolved Analytics LLC, a data science and system design, software and solutions provider ([www.evolved-analytics.com](http://www.evolved-analytics.com)). Prior to assuming this role, she spent 23 years in executive and leadership positions at Dow Chemical, including most recently, the Vice President for Sustainable Technologies and Innovation Sourcing. From 2005-2010, she served as the Chief Technology Officer of Dow Chemical China Company Limited, leading Asia Pacific R&D, including the development of Dow's state-of-the-art 1 million square foot R&D center in Shanghai, China and the staffing of >1200 scientists and engineers across the region. Over the course of her Dow tenure, she held numerous business and corporate roles, including Global R&D Director in Dow Plastics, Dow Ventures and Corporate R&D. In 2011-2012, she served as the industrial led and working group co-chair of President Obama's Advanced Manufacturing Partnership Initiative.

Kotanchek holds a doctorate in Materials Science, a masters of science in Ceramic Science, and a bachelor of science in Ceramic Science & Engineering from The Pennsylvania State University. She has published over 100 technical articles, holds 6 US patents and has given over 200 invited talks. She is an active member of the American Chemical Society, Materials Research Society, Council of Industrial Research and Society of Women Engineers. She has served on the Shanghai American Chamber of Congress Science & Technology Subcommittee, and is currently serving on the US National Academy of Engineers "Making Value for America" Committee. She also serves on numerous university External Advisory Boards, including Penn State, Georgia Tech and University of Michigan.



Dr. Rob Maskell  
Chief Scientist of Cytec  
Engineered Materials

Rob Maskell is Chief Scientist of Cytec Engineered Materials, a business unit of Cytec Industries Inc. Dr. Maskell has over 25 years experience in the advanced composite materials industry; specializing in advanced reinforced polymer matrix materials for both primary and secondary structural aerospace applications. He began his early career with Imperial Chemical Industries PLC (UK) and has since held positions of increasing responsibility in the areas of Product Development and Strategic Research and Technology. In his most recent role Rob exploits Technology Roadmapping as an advanced methodology to intercept future unmet customer needs.

Dr. Maskell received a BSc in Chemistry from the University of Bath and a PhD from the University of Sussex. He currently resides in Phoenix, Arizona (USA).

## EXTERNAL ADVISORY BOARD



Dr. Michael F. McGrath  
Retired - Analytic Services  
Inc. (ANSER)

Michael F. McGrath retired as a corporate officer of Analytic Services Inc., a not-for-profit public service research institute. He led ANSER's operations in Science and Technology and Operations Analysis and Management support. Prior to joining ANSER in 2007, he served as Deputy Assistant Secretary of the Navy for Research, Development, Test, and Evaluation (RDT&E). In that role, he was the Navy's senior civilian advocate for technology transition and for the T&E enterprise. His prior industry experience includes five years as Vice President for Government Business at the Sarnoff Corporation, a leading R&D company with both commercial and government clients. His prior government experience started with engineering positions in logistics at NAVAIR in the 1970s, acquisition at Office of the Secretary of Defense (OSD) in the 1980s, and Science and Technology at DARPA in the 1990s. In OSD, he was the principal author of the DoD policy directive on Integrated Logistics Support and the first director of the Computer-aided Acquisition and Logistics Support (CALs) program. In DARPA's Defense Sciences Office, he managed programs in Dual Use Science and Technology, Agile Manufacturing, Electronic Commerce Resource Centers, and Affordable Multi Missile Manufacturing. He also served in leadership positions for several DoD-wide initiatives to improve manufacturing and reduce the cost of defense systems. He is currently a member of the National Research Council's Materials and Manufacturing Board and the Defense Materials, Manufacturing and Infrastructure Committee. He has served on several Defense Science Board task forces.

Dr. McGrath holds a BS in Space Science and Applied Physics and an MS in Aerospace Engineering, both from Catholic University, and a doctorate in Operations Research from George Washington University.



Don Mottaz  
Director – Assembly and  
Integration Technology  
Boeing Research &  
Technology

Don is the Director for Assembly and Integration for Boeing Research and Technology (BR&T). In his current assignment he leads of a team of 300 engineers and technicians with responsibility for the development and implementation of technologies used for the assembly of Boeing products. This includes robotic/ automated assembly systems for component buildup, and wings and fuselages assembly, the application of smart tools and information systems to the factory floor to improve assembly methods and situational awareness in manufacturing, new drilling and fastener systems, augmented reality technologies and factory infrastructure projects to improve part logistics and delivery throughout the supply chain.

Prior to his current assignment, Don served as the Director for Materials and Process Technology (M&PT) support to BCA programs and M&PT Chief Engineer for BCA Product Development. Don has held assignment supporting all areas of commercial aircraft manufacturing and design, as well as leading the M&PT Technology Development activities. Don's 33 plus years experience covers all areas of manufacturing operations from detail part manufacturing, chemical finishing and processing, sub structure assembly and major aircraft structure join, systems installation, functional test and final paint and delivery. Don has extensive experience in the in the development and introduction of new materials and process into the manufacturing of commercial airplanes.

Don was born in California and grew up in Eastern Washington. He has a Bachelor of Science in Chemical Engineering and an MBA from the University of Washington in Seattle



## EXTERNAL ADVISORY BOARD



Dr. John D. Russell  
Program Manager of  
the DMS&T Program on  
behalf of the Office of the  
Secretary of Defense's  
Manufacturing and  
Industrial Base Policy

John D. Russell is the Program Manager of the DMS&T Program on behalf of the Office of the Secretary of Defense's Manufacturing and Industrial Base Policy office. In this role, he is responsible for planning and executing manufacturing technology programs to mature cross-cutting defense manufacturing needs and to stimulate early development of manufacturing processes and enterprise business practices concurrent with S&T development. In this role, he collaborates with the manufacturing technology community across the Department of Defense (DoD).

Russell began his career with the Air Force Research Laboratory (AFRL) in 1989, researching organic matrix composites. From 2000-2006, he was the Government's program manager for the Composites Affordability Initiative (CAI), the DoD's largest ever composites R&D program, where he led a consortium of aircraft manufacturers to reduce the cost of composite airframes through the use of large integrated and bonded structures. From 2007-2008, John launched AFRL's Advanced Manufacturing Propulsion Initiative, aiming to reinvigorate the US propulsion companies and their supplier base with advanced manufacturing technologies and to improve cost and cycle times for the F-35's engines. From 2008-2010, he was the AFRL's manufacturing lead on the X-55A Advanced Composite Cargo Aircraft (ACCA) program, which built and flew a composite cargo demonstration airplane as a capstone demonstration of the technologies developed under CAI.

He has a Bachelor of Chemical Engineering degree and a Master of Science in Materials Engineering degree from the University of Dayton in Dayton, OH and a Doctor of Science degree in chemical engineering from Washington University in St Louis. Dr. Russell is the winner of the 2010 AFRL Commander's Cup for his work on ACCA, and was inducted as a Fellow of the Society for the Advancement for Materials and Process Engineering (SAMPE) in 2011.



Peter Sigmon  
Vice President of  
Innovation  
Shaw Industries

Peter Sigmon has for five years served as Shaw Industries' Vice President of Innovation overseeing Corporate Strategic Innovation, Residential Research and Development, Fiber and Yarn Innovation, and Materials Recovery. Shaw Industries, a subsidiary of Berkshire Hathaway, Inc., is the world's largest carpet manufacturer and a leading floor covering provider with more than \$4 billion in annual sales and approximately 25,000 associates. Headquartered in Dalton, Ga., the company manufactures and distributes carpeting, rugs, hardwood, laminate, resilient, tile/stone and synthetic turf for residential and commercial applications worldwide. Sigmon joined Shaw Industries in 1999 serving first as Director and later Vice President of Research and Development for Shaw's Commercial Floorcovering division.

A 1984 graduate of North Carolina State University, where he studied Textile Management, Sigmon worked for BASF Corporation's Fibers Division and Pharr Yarns & Company in fiber and yarn product development and technical sales from 1984 until 1999. He is a member of Shaw's Growth & Sustainability Council and chairs the Eco Products Charter Team. Pete is an active member of the Conference Board's - Council of Innovation, and he participates in the Georgia Next Generation Manufacturing Program. Sigmon, his wife Lisa and three children live in Dalton, Ga.

## EXTERNAL ADVISORY BOARD



Dr. Charles Wessner  
Founder and Director  
National Academy of  
Sciences Technology,  
Innovation, and  
Entrepreneurship Program

Dr. Charles Wessner is a distinguished scholar and a powerful advocate of effective innovation policies. He is the founder and Director of the National Academy of Sciences Technology, Innovation, and Entrepreneurship Program. He is recognized nationally and internationally for his expertise on innovation policy, including public-private partnerships, entrepreneurship, early-stage financing for new firms, and the special needs and benefits of high-technology industry. He works closely with the U.S. Congress, the White House, and major agencies and departments of the U.S. government. As an outgrowth of his work with the U.S. government, he advises technology agencies, government ministries, and the Prime Ministers of countries in Europe and Asia. In addition, he cooperates closely with international organizations and lectures at major universities in the U.S. and abroad.

Reflecting his strong global interest in innovation and policy expertise, Wessner is frequently asked to address issues of shared policy interest with foreign governments, universities, and research institutes, often briefing government ministers and senior officials. He frequently gives keynote addresses and presentations to international organizations such as UNCTAD, the UN Economic Commissions for Europe and for Latin America, the World Bank, the Inter-American Development Bank, the OECD, and the European Investment Bank, as well as the European Commission. In Washington, he works closely with Congress, the White House, and major departments and agencies in the executive branch on the formulation of effective innovation policy.

Wessner has served as advisor to the 30-nation OECD Committee on Science and Technology Policy, as a member of the Canadian Council of Academies' Expert Committee on Science and Technology in Canada, as advisor to the national technology agencies of Finland (TEKES) and Sweden (VINNOVA), and as a member of the Norwegian Technology Forum.



## GEORGIA TECH FACULTY BIOGRAPHIES



Dr. Stephen Cross  
Executive Vice  
President for Research  
Georgia Institute of  
Technology

Chief Research Officer

In addition to serving as Georgia Tech's Executive Vice President for Research, Stephen E. Cross is a professor in the H. Milton Stewart School of Industrial and Systems Engineering and an adjunct professor in the College of Computing and the Ernest J. Scheller College of Business. He served as a Vice President and Director of the Georgia Tech Research Institute from 2003 to 2010.

Previously, Cross was at Carnegie Mellon University as a research faculty member in computer science and Director and CEO of the Software Engineering Institute. Earlier, he was a program manager at the Defense Advanced Research Projects Agency and a faculty member at the Air Force Institute of Technology. A retired military officer, he received the Air Force Research Award in 1986 and the Federal 100 Award in 1992.

Cross is a member of the Defense Science Board. A past member of the Air Force Scientific Advisory Board, he has supported studies by the National Research Council, testified to Congress, and served as a consultant to government and industry. He has published widely on artificial intelligence, software engineering, and technology transition. Cross is a Fellow of the Institute of Electrical and Electronic Engineers (IEEE) and a former Editor-in-Chief of IEEE Intelligent Systems. He is currently an Associate Editor of the Journal of Information, Knowledge, and Systems Management.

He received his BSEE from the University of Cincinnati, his MSEE from the Air Force Institute of Technology, and his PhD from the University of Illinois at Urbana-Champaign. He received his Professional Engineer certification in Ohio in 1978.



Dr. Ben Wang  
Executive Director,  
Georgia Tech  
Manufacturing Institute

Gwaltney Chair in  
Manufacturing Systems,  
Georgia Tech College of  
Engineering

Chief Manufacturing Officer

Dr. Ben Wang currently serves as the executive director of the Georgia Tech Manufacturing Institute and is the chief manufacturing officer for the Institute.

In addition to his roles at Georgia Tech, Dr. Ben Wang also serves on the U.S. National Materials and Manufacturing Board of the National Research Council, and is a Fellow of the Institute of Industrial Engineers, the Society of Manufacturing Engineers, and the Society for the Advancement of Material and Process Engineering.

Dr. Wang's research focuses on applying emerging technologies to improve manufacturing competitiveness. His work in advanced materials and manufacturing has resulted in several invitations from the White House. He has presented to the U.S. National Research Council Review Panel in support of the U.S. National Nanotechnology Initiative and to the National Academies Committee on Manufacturing Extension Partnership. In 2012, he participated in the White House Roundtable on Strengthening U.S. Advanced Manufacturing in Clean Energy.

Dr. Wang has authored or co-authored more than 220 refereed journal papers and 150 conference articles. He has a portfolio of issued and applied-for patents that now exceeds 25, and 15 of which have been licensed for commercialization.

## GEORGIA TECH FACULTY BIOGRAPHIES



Dr. Jennifer Clark  
Associate Professor  
School of Public Policy  
Director of the Center for  
Urban Innovation  
Georgia Tech

Jennifer Clark is an Associate Professor in the School of Public Policy and Director of the Center for Urban Innovation. Her research focuses on the development and diffusion of regional policies and their effect on cities and their economic resilience. Her newest book, *Working Regions: Reconnecting Innovation and Production in the Knowledge Economy* (2013) focuses on policy models aimed at rebuilding the links between innovation and manufacturing in the U.S. Her first book, *Remaking Regional Economies: Power, Labor, and Firm Strategies in the Knowledge Economy* (with Susan Christopherson) won the Best Book Award from the Regional Studies Association in 2009. Dr. Clark's second book, *Basic Methods of Policy Analysis and Planning* (with Carl Patton and David Sawicki) is widely adopted in policy and planning courses. She is also the co-editor of the forthcoming *Handbook of Manufacturing Industries in the World Economy* with John Bryson and Vida Vanchan (f 2015).

Dr. Clark has collaborated on manufacturing and innovation policy projects with a broad range of governments and non-governmental organizations including the OECD and the Canadian, UK, and US governments. She currently serves as an economic advisor to The Essential Economy Council, a commissioner on the Miller Center's New Manufacturing Commission and a visiting fellow with the Institute of Advanced Studies at the University of Birmingham, UK. Since the mid-1990s, Dr. Clark has studied the spatial and organizational dynamics of the optics, imaging, and photonics industry both in the U.S. and internationally. At Georgia Tech, Dr. Clark teaches courses on urban and regional economic development theory, analysis, and practice as well as research design and methods.

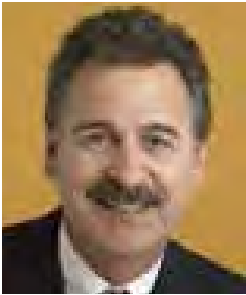


Dr. Richard Cowan, P.E.  
Senior Research Scientist,  
Director, Laboratory for  
Extreme Tribology &  
Diagnostics  
Georgia Tech Manufacturing  
Institute

Dr. Richard S. Cowan (Ph.D. 2002, MSME 1992, Georgia Tech) is a Senior Research Scientist, Director, Laboratory for Extreme Tribology & Diagnostics. His professional interests include the strategic management of technology, equipment asset management and surface engineering, including thermal phenomena, wear, and fatigue. He has held engineering and management positions at TRW Bearings Division (presently SKF Aeroengine North America) and Cummins Engine Company. He is a Professional Engineer, registered in the State of New York.

Dr. Cowan was named a Federal Congressional Fellow by the American Society of Mechanical Engineers (ASME) in 1998. In 2012, he was named a US delegate to the International Tribology Council, and honored with the Donald Wilcock Award from the ASME Tribology Division for distinguished service to the tribology community throughout his professional career. A co-recipient of the Saturn Company Award for Teamwork, Dr. Cowan presently serves as Lead of the Engineering Sciences Segment of ASME.

## GEORGIA TECH FACULTY BIOGRAPHIES



Chris Downing, P.E.  
Associate Vice President  
Enterprise Innovation  
Institute  
Georgia Tech

Associate Vice President of the Enterprise Innovation Institute at Georgia Tech, Chris Downing has over 25 years of leadership experience at Georgia Tech in technology-based economic development, university outreach and technical assistance, entrepreneurship and start-up support, and program management. Downing has served in a number of capacities in the development of the Enterprise Innovation Institute, Georgia Tech's primary service and outreach organization. His roles have included Director of the Georgia Manufacturing Extension Partnership (GaMEP), Associate Director of the ATDC incubator, COO of Emtech Bio, and several years as a research engineer with the Georgia Tech Research Institute.

Downing played a key role in the expansion of ATDC startup activities into the life sciences area and expansion of ATDC at Technology Square to include corporate landing and collaboration space. Downing's engineering expertise includes building energy efficiency and energy recovery systems, mechanical facilities design, indoor air quality, and manufacturing process systems.

Prior to joining Georgia Tech, Downing was a mechanical engineer with IBM, specializing in manufacturing facility development and energy efficiency programs.

He is a registered professional engineer in Georgia and Florida and holds a B.S. and M.S. in mechanical engineering from the University of Florida. He serves on the boards of several organizations, including the Technology Association of Georgia (TAG) Manufacturing Society, Next Generation Manufacturing of Georgia, and the Executive Board of the Georgia Tech Faculty.



Dr. Soumen Ghosh  
Professor of Operations  
and Supply Chain  
Management  
Scheller College of  
Business at  
Georgia Tech

Soumen Ghosh is a Professor of operations and supply chain management in the Scheller College of Business at Georgia Institute of Technology (Georgia Tech). He is also the Faculty Director for non-degree and custom executive education programs for corporate customers. He formerly served as the Director of the Center for Quality and Change Leadership at Georgia Tech for eight years. His primary areas of expertise are in supply chain excellence capability development, supply chain executive leadership development, operations and supply chain strategy for competitive advantage, global supply chain and operations/ manufacturing capability development, and strategic supply chain infrastructure development.

He is also the Academic Director of supply chain excellence executive education programs for corporate customers. In addition, he provides consulting and training services to organizations in several countries in the areas of operations/manufacturing and supply chain strategy and capability development. He frequently conducts professional workshops on operations and supply chain excellence in many countries, and is also a frequent speaker at conferences and company events. Professor Ghosh's work experience is in the manufacturing/operations and supply chain area in the auto industry.

On the academic front, Professor Ghosh serves on the Editorial Boards of several leading academic journals in the operations and supply chain management field, and his research has been published in several scholarly journals – he has published over 100 papers and conference proceedings in the overall operations and supply chain domain.

He received his Ph.D. in Operations Management, and M.S. in Industrial & Systems Engineering from The Ohio State University. He holds a B.S. in Mechanical Engineering from the Birla Institute of Technology (India).

## GEORGIA TECH FACULTY BIOGRAPHIES



Dr. Krishnendu (Krish) Roy  
Carol Ann and David D.  
Flanagan Professor  
Director, Center for  
Immunoengineering at  
Georgia Tech  
The Wallace H. Coulter  
Department of Biomedical  
Engineering at Georgia Tech  
and Emory University

Dr. Krishnendu (Krish) Roy received his undergraduate degree from the Indian Institute of Technology (India) followed by his MS from Boston University and his PhD in Biomedical Engineering from Johns Hopkins University. Following his PhD, he joined Zycos Inc., a start-up biotechnology company where he served first as a Scientist and then as a Senior Scientist in the Drug Delivery Research group. Dr. Roy left his industrial position to join The University of Texas at Austin in 2002, where he was most recently Professor and Fellow of the Cockrell Chair in Engineering Excellence. He left UT-Austin in July of 2013 to move to Georgia Tech where he is currently the Flanagan Professor of Biomedical Engineering and Wallace H. Coulter Distinguished Faculty Fellow. Dr. Roy's research interests are in the areas of controlled drug and vaccine delivery technologies, Immuno-engineering and stem cell engineering with particular focus in biomedical materials with applications in cancer and immunotherapies. In recognition of his seminal contribution to these fields, Dr. Roy has been elected Fellow of the American Institute for Medical and Biological Engineering (AIMBE) and Fellow of the Biomedical Engineering Society (BMES). In addition, Dr. Roy has received numerous awards and honors including Young Investigator Awards from both the Controlled Release Society (CRS) and The Society for Biomaterials (SFB), the Young Scientist Award from HSEMB, NSF CAREER award, Global Indus Technovator Award from MIT, the CRS Cygnus Award etc. He has also received the translational research award from the Coulter foundation and the bioengineering grant from the Whitaker Foundation. He is the Editor of the Springer Publication book "Biomaterials as Stem Cell Niche". Dr. Roy's research has been supported continually by the NIH and NSF as well as the Cancer Prevention and Research Institute of Texas (CPRIT). He serves as a member of the Editorial Boards of the Journal of Controlled Release and the European Journal of Pharmaceutics and Biopharmaceutics.



Dr. Chelsea (Chip) White  
Schneider National Chair in  
Transportation and Logistics  
H. Milton Stewart School  
of Industrial and Systems  
Engineering  
Georgia Tech College of  
Engineering

Chelsea C. White III received his Ph.D. from the University of Michigan (UM) in 1974 in Computer, Information, and Control Engineering. He has served on the faculties of the University of Virginia (1976 - 1990) and UM (1990 - 2001). He has served as school chair of the Stewart School of Industrial & Systems Engineering (2005-10) and holds the Schneider National Chair of Transportation and Logistics at the Georgia Institute of Technology, where he is the former director of the Trucking Industry Program (TIP) and the former executive director of The Logistics Institute. He serves on the boards of directors for Con-way, Inc. (NYSE: CNW), The Logistics Institute-Asia Pacific, the Industry Studies Association, and the Bobby Dodd Institute, and is a former member of the board of ITS America (a Utilized Federal Advisory Committee) and the ITS World Congress.

His involvement with the IEEE includes serving as President of the Systems, Man, and Cybernetics (SMC) Society (1992 - 93). He received the Norbert Wiener Award in 1999 and the Joseph G. Wohl Outstanding Career Award in 2005, both from the IEEE SMC Society, and an IEEE Third Millennium Medal. The Norbert Wiener Award is the SMC's highest award recognizing lifetime contributions in research. He is the recipient of the 2008 IEEE ITSS ITS Outstanding Research Award for "significant contributions in research and development in global transportation and logistic systems." He is a Fellow of the IEEE, a Fellow of INFORMS, a former member of the Executive Board of CIEADH (Council of Industrial Engineering Academic Department Heads), and the founding chair of the IEEE TAB Committee on ITS (now an IEEE Society). He is a former member of the World Economic Forum trade facilitation council. He is currently the Systems Strategies theme leader for the DHS National Center for Food Protection and Defense and the Industry Studies Association liaison to INFORMS.



## GEORGIA TECH FACULTY BIOGRAPHIES



Dr. Chuck Zhang  
Professor  
H. Milton Stewart  
School of Industrial and  
Systems Engineering

Chuck Zhang received his Ph.D. degree in Industrial Engineering from the University of Iowa. Prior to the doctoral degree, he received an M.S. degree in Industrial Engineering from the State University of New York at Buffalo, and B.S. and M.S. degrees in Mechanical Engineering from Nanjing University of Aeronautics and Astronautics in China. Prior to joining ISyE, Zhang served as a professor and chairman of the Department of Industrial and Manufacturing Engineering at the Florida A&M University - Florida State University College of Engineering.

Zhang's research interests include additive manufacturing (3D printing and printed electronics), scalable nanomanufacturing, integrated computational materials and manufacturing engineering, composites and nanocomposites manufacturing, geometric dimensioning and tolerancing, and metrology. Most recently, he has initiated new research and education programs in advanced materials and manufacturing engineering for orthotics and prosthetics (O&P) applications. His research projects have been sponsored by a number of organizations, including the Air Force Office of Scientific Research, Army Research Laboratory, National Institute of Standards and Technology, National Science Foundation, Office of Naval Research, and Society of Manufacturing Engineers, as well as industrial companies such as ATK Launch Systems, Cummins, General Dynamics, GKN Aerospace Services, Lockheed Martin, and Siemens Power Generation.

Strategic Planning Report





## Strategic Planning Report

## Committee Report

- ➔ • Georgia Tech's Vision and Strategy
- GTMI Strategy and Operating Approach
- GTMI Strategy Execution
- Summary and Next Steps

12/11/14

3

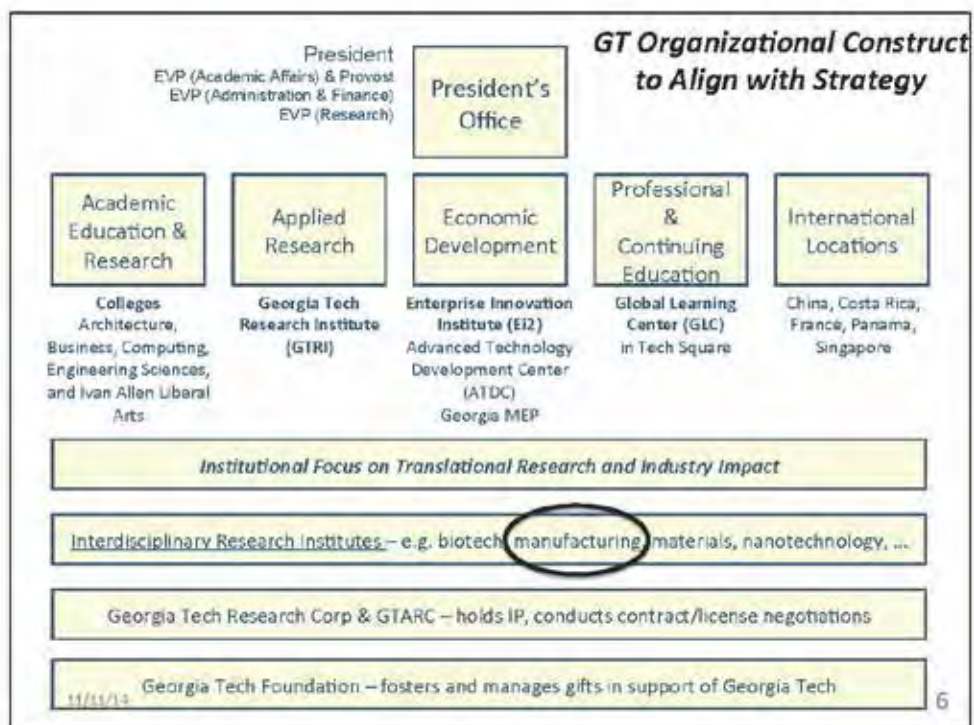
## Georgia Tech's Vision

Georgia Tech will define the technological research university of the 21st century.

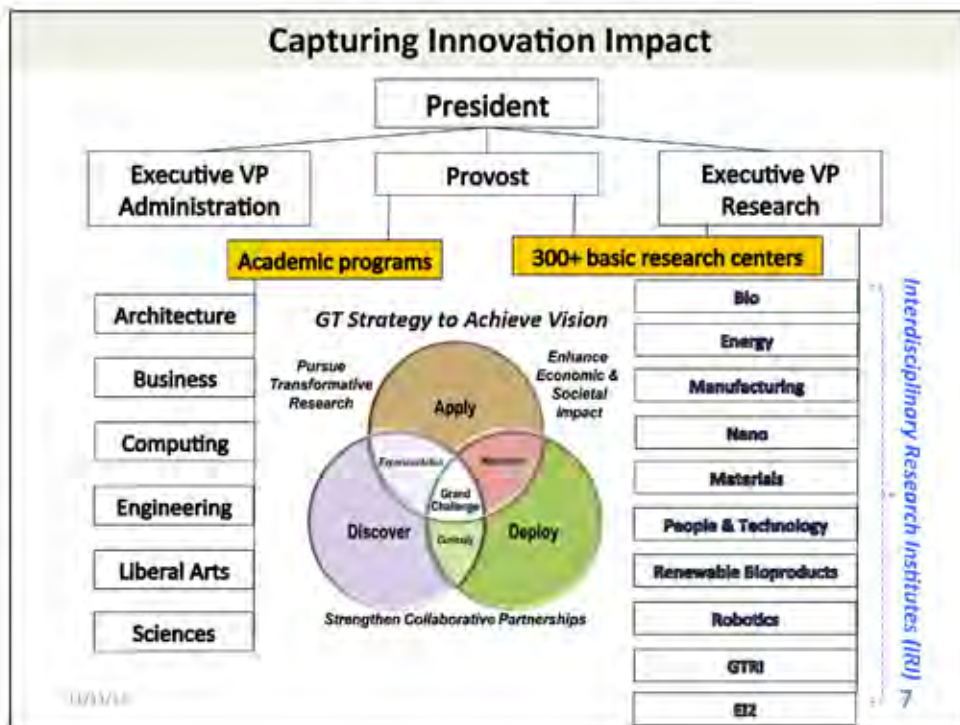
As a result, we will be leaders in influencing major technological, social, and policy decisions that address critical global challenges.

4

Strategic Planning Report



# Strategic Planning Report



## Committee Report

- ➔ • GTMI Strategy and Operating Approach
- GTMI Strategy Execution
- Summary and Next Steps



Strategic Planning Report

**GTMI Vision**

*GTMI will be the world's premier institution anticipating needs and providing solutions on the frontiers of manufacturing research, application, and deployment.*

**GTMI Mission**

*To pursue knowledge and skills that accelerate the translation of manufacturing-related research into high impact products and manufacturing systems*

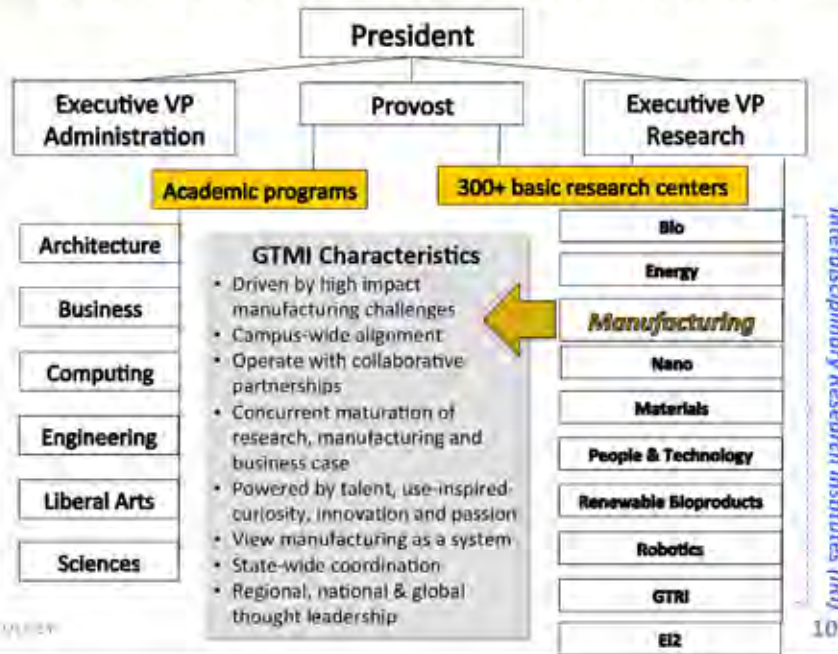
**A Major Outcome**

*As a result, we will be leaders in major technological, social, and policy decisions that address critical manufacturing challenges.*

GTMI

9

**GTMI's Mission-Driven Operating Characteristics**



GTMI

Strategic Planning Report

### GTMI Strategic Imperatives ...Mission-Driven

- Engage partners to foster and sustain manufacturing capabilities networks aligned with opportunities to address high-impact manufacturing challenges.
- Leverage and champion Georgia Tech's tradition of excellence in across-campus manufacturing-related knowledge, basic research and interdisciplinary applied research.
- Accelerate application and deployment of manufacturing innovation by collaboratively, concurrently, and aggressively maturing technology, manufacturing and business case readiness.

11



Strategic Planning Report

### Agenda for Committee Report

- Georgia Tech's Vision and Strategy
- GTMI Strategy and Operating Approach
- ➔ • GTMI Strategy Execution
- Summary and Next Steps

13





## Strategic Planning Report

## GTMI Internal Advisory Board (IAB) Strategy Execution Roles

### INTENDED ROLES

*Advise and assist* the GTMI Executive Director in:

- establishing an inventory of GT leaders and their across-campus manufacturing-related research (on-going effort).
- the execution of the GTMI mission and strategy, including:
  1. Analyzing and prioritizing Manufacturing Challenges.
  2. Identifying existing skills, capabilities and gaps in knowledge and resources needed to address each challenge
  3. Building relationships with other institutions having capabilities that fill key gaps.
  4. Mentoring GTMI stakeholders to enable accelerated technology deployment.
  5. Working with the GTMI EAB in evaluating what is needed to address each challenge (including external capabilities and potential sponsors)

### MEMBERSHIP

The IAB shall consist of 8-12 members. To be a GTMI IAB member, eligible to serve on the IAB, one must share and embrace the idea of conducting collaborative research and support the vision, mission and strategic imperatives of GTMI

15

## GTMI External Advisory Board (EAB) Strategy Execution Roles

### INTENDED ROLES

*Advise and assist* the GTMI Executive Director in:

- assuring the EAB skill sets are aligned with the scope of GTMI needs (on going)
- the execution of the GTMI mission and strategy, including:
  1. Identifying and prioritizing Manufacturing Challenges.
  2. Clarifying the impacts and risks associated with addressing each challenge.
  3. Structuring partnerships and skill sets consistent with the GTMI Strategy.
  4. Building external relationships with other institutions having capabilities that fill key gaps.
  5. Working with the GTMI IAB in evaluating what is needed to address each challenge (including external capabilities and potential sponsors)

### MEMBERSHIP

The GTMI EAB shall consist of 10-15 members. To be an EAB member one must share and embrace the ideas of viewing manufacturing as a system, and identifying high impact manufacturing challenges that drive collaborative and concurrent technology development in support of the GTMI vision, mission and strategy.

16

## Strategic Planning Report

## Agenda for Committee Report

- Georgia Tech's Vision and Strategy
- GTMI Strategy and Operating Approach
- GTMI Strategy Execution
- ➔ • Summary and Next Steps

11/12/14

17

## GTMI Strategic Planning Committee

### ...Summary and Next Steps

- SPC Report Summary
  - GTMI vision, mission, strategy and operating approach are aligned with GT's vision of a 21<sup>st</sup> Century technological research Institute
  - GTMI mission success will provide new offerings to GT customers and catalyze new knowledge, skills and thought leadership among our stakeholders, faculty and students
  - Execution of the GTMI operating approach, including 12 initial acceleration levers, is in early deployment
- Recommended Next Step
  - "Alpha-test" the execution of the GTMI operating approach, with its 12 initial acceleration levers, at the November EAB

11/12/14

18

## Overview of Alpha Test Approach

## Today's Alpha Test Approach and Expectations

12 November 2014

Mike McGrath

Bill Kessler



## Elements of Today's "Alpha Test"

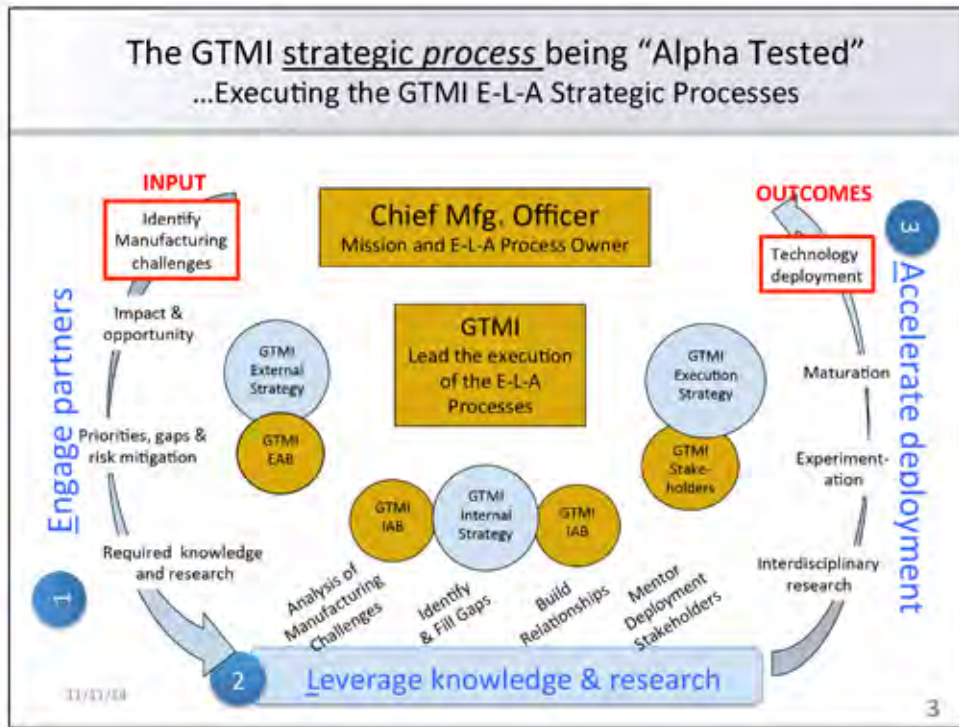
- The GTMI strategic process being alpha tested is..
  - the execution of the *GTMI E-L-A Strategic Processes* (Operating Approach) that provides high impact GTMI mission outcomes
- The identified GTMI process features for evaluation are..
  - the twelve defined *acceleration levers* for the execution of the E-L-A Strategic Processes.
- A range of GTMI exemplar Manufacturing Challenges have been selected for today's alpha test
- The expected outcome from the alpha test include..
  - launching the thought process for creating a template that assists GTMI in accelerating translation of research into products and manufacturing systems.

11/11/14

2



Overview of Alpha Test Approach



	Acceleration Levers	Criteria
Engage Partners	1.1 Identify Manufacturing Challenges	
	1.2 Impact and Opportunity	
	1.3 Priorities and Risk Management	
	1.4 Required Knowledge and Research	
Leverage GT Capabilities	2.1 Analysis of Manufacturing Challenges	
	2.2 Skills and Capabilities Gaps	
	2.3 Build Relationships	
	2.4 Mentor Stakeholders	
Accelerate Deployment	3.1 Interdisciplinary Research	
	3.2 Experimentation	
	3.3 Maturation	
	3.4 Technology Deployment	
	Other -	
	Other -	

GTMI Template of Acceleration Levers and "to be established" Criteria

## Overview of Alpha Test Approach

**GTMI Manufacturing Challenges**

... GTMI initial description

- High-payoff interdisciplinary research that bridges the gap between fundamental discoveries and high impact practical use.
  - Help tackle important problems in areas that include energy, health, education, the environment, national security, and global development;
  - Help create the industries and jobs of the future;
  - Expand the frontiers of human knowledge; and
  - Serve as a “North Star” for collaboration between the public and private sectors.

11/11/14

5

**GTMI Meta Strategy for**

...Identifying Potential GTMI Manufacturing Challenges

**Alignment** -- with GTMI Vision, Mission and Strategy

**Impact** – Economic, National Security, and Societal

**Disciplines Required** – Science, Engineering, Business, and Policies

**SWOT** – GTMI, GT, External and Internal Entities

**Readiness** – Technology, Manufacturing, Business, and Ecosystem

**Partners** -- with “skin in the game”

11/11/14

6

## Overview of Alpha Test Approach

**The Exemplar Challenges for Today's "Alpha Testing"**

- **High Impact National Manufacturing Initiatives**
  - Accelerated Innovation and Insertion of Advanced Composites
  - Cell Bio-Manufacturing Technologies and Standards
- **Frontiers of Manufacturing as a System**
  - Trends in Logistics and Supply Networks
  - Innovation in Incubators and Beyond for Achieving Maturation
- **Manufacturing that Innovates and Enables "Grand Challenges"**
  - Regulatory: Material and manufacturing implications of new CAFE Standards
  - DARPA: Hypersonic capabilities

11/11/14

7

**Today's Alpha Test GTMI Execution Strategy  
... Expectations**

- 20 minute review of specific exemplar, including
  - What is the Potential Manufacturing Challenge?
  - What is the Impact of Success?
  - Externally, who Requires the Results and Why?
  - What Internal GT Disciplines/Organizations are Involved/Needed?
  - What External Involvement Exists/Needed?
  - What are Current Limitations (funding, research gaps, etc.)?
- 25 minute facilitated session focused on the thought process for prioritizing and strengthening the acceleration levers for the specific exemplar:
  - Which are *most important acceleration levers* for the exemplar?
  - What is *most important information required before commitment* as a GTMI Challenge pursuit?

11/11/14

8



Alpha Test 1

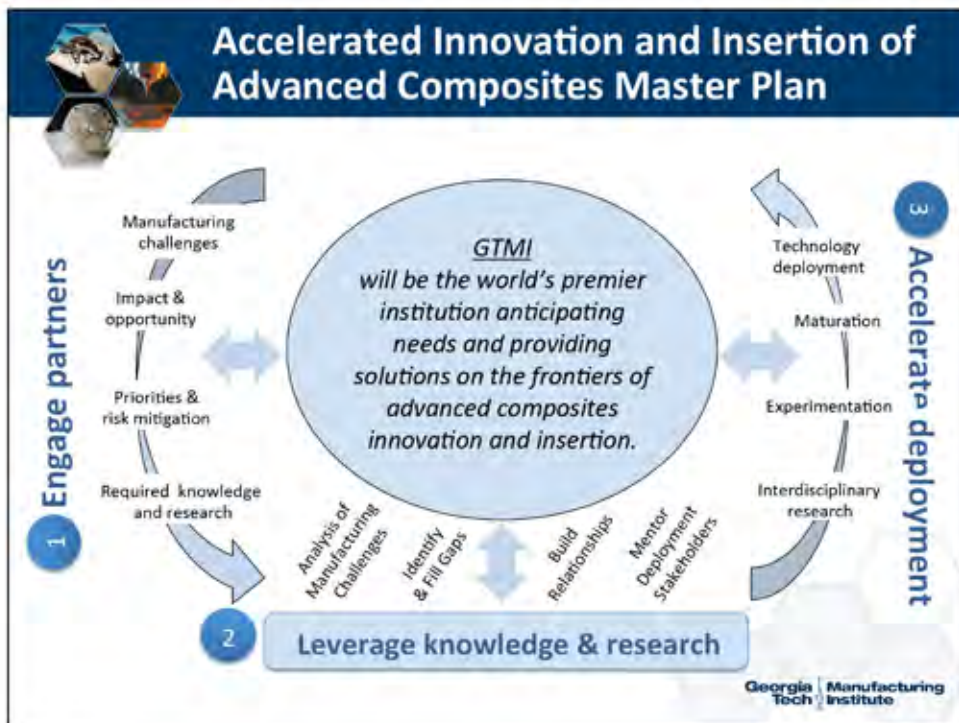


**Manufacturing Challenge Exemplar:  
Accelerated Innovation and Insertion  
of Advanced Composites**

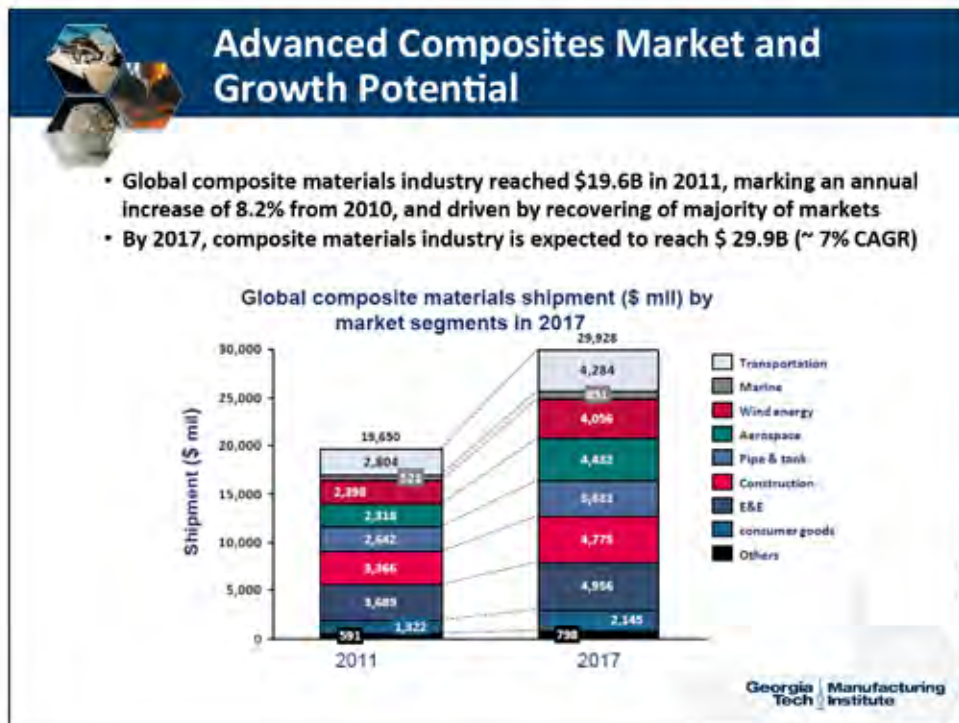
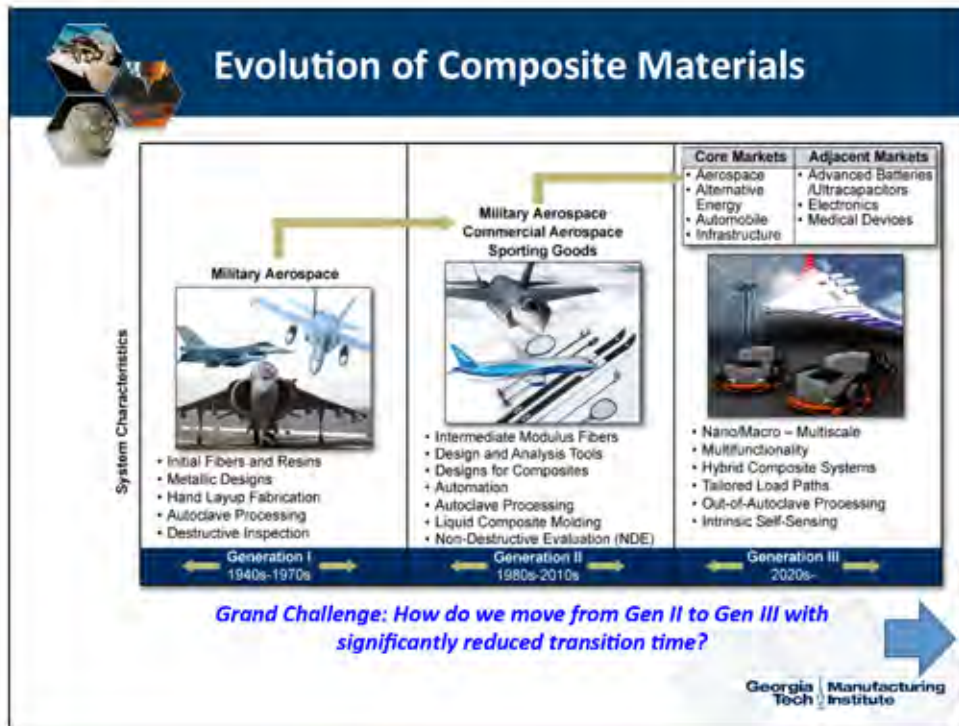
Chuck Zhang  
School of Industrial & Systems Engineering  
and Georgia Tech Manufacturing Institute

November 12, 2014

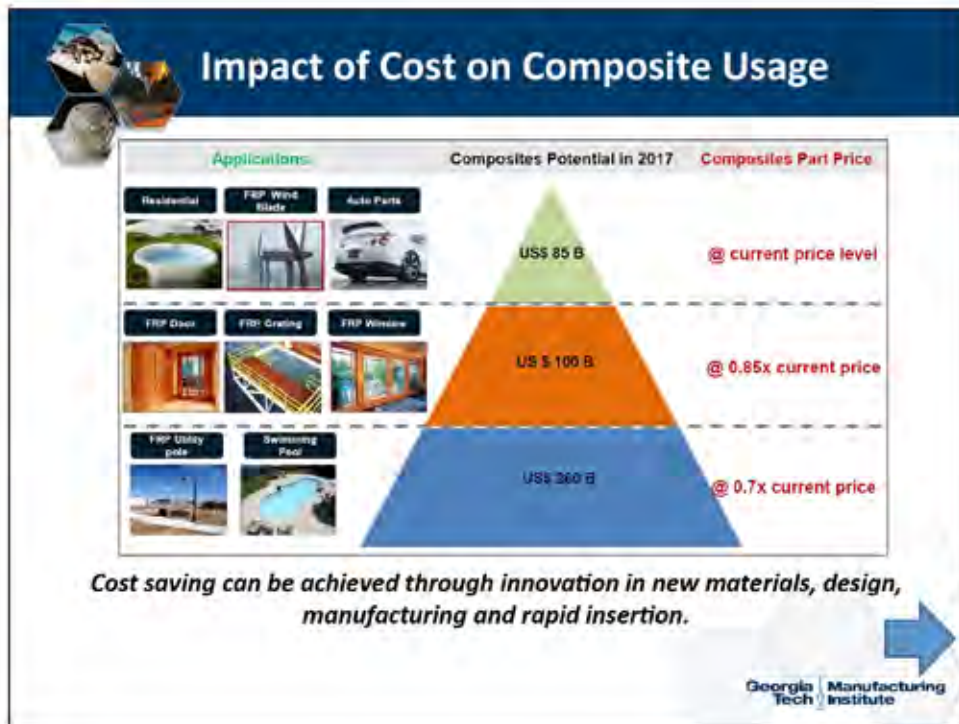
**Georgia Tech Manufacturing Institute**



# Alpha Test 1



## Alpha Test 1



### NIST AMTech Award: Consortium for Accelerated Innovation and Insertion of Advanced Composites (CAIIAC)

**Goals:**

- Develop an objective, verifiable and consistent roadmap to identify and validate emerging cross-cutting composite technologies
- Create a domestic innovation manufacturing ecosystem to accelerate advanced composite products into the market

**Mission:**

- Accelerate innovation and assist rapid insertion of advanced composites
- Develop broad-based applications for advanced composites
- Encourage “invent here, build here” in the United States to improve U.S. competitiveness and sell advanced composite products globally

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## Alpha Test 1

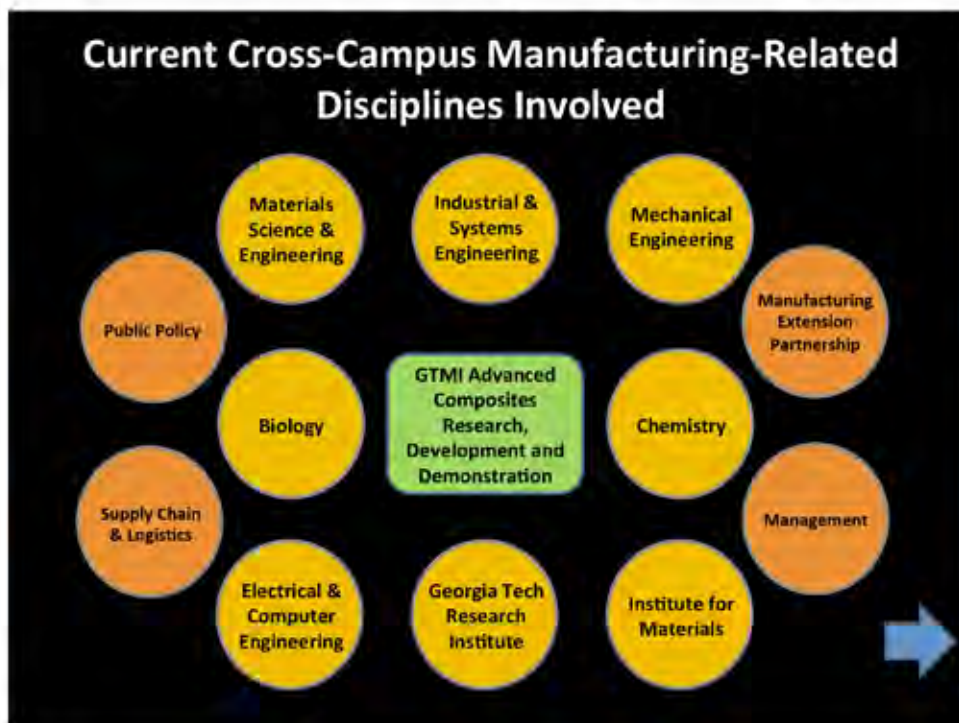


### Grand Technical Challenges Related to Advanced Composites Innovation and Insertion

**CAIAC Starter Set Based on Polling Key Leaders:**

- Standardized composite design and testing for faster and more affordable certifications
- Scalable, fast and reproducible out-of-autoclave processes and affordable tooling
- Quick and reliable joining and repairs
- Inclusion of nanomaterials for improved performance
- Structural health monitoring of life cycle performance
- Recycling and reuse of composites

*Cost, Quality/Reproducibility, Efficiency*



## Alpha Test 1



### External Stakeholders

- **Industry partners for technology insertion and workforce**
  - Over 40 companies expressing interest in CAIAC
  - Many other potential partners
- **Government agencies and sponsors for technology development**
  - NIST, NSF, DOD, DOE, DARPA, FAA, USDA, etc.
- **Trade associations for industry growth**
  - ACC, ACMA, SAMPE, etc.
- **State and local governments for economic development and growth**

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## Alpha Test 1



## Existing External Involvement

- Interview of domain experts
- CAIAC workshop (Nov. 5, 2014)
  - Two more workshops planned in 2015
- Discussion for potential projects with industry partners
  - Boeing, Lockheed, Sikorsky, ThyssenKrupp, etc.
- Partnerships with external units for funding
  - Universities: FSU, TAMU, UConn, UDayton, etc.
  - Companies: Lumense, OG Tech, Optomec, Softwear, etc.
- Partnerships for economic development and workforce training
  - Georgia Manufacturing Extension Partnership
  - Technical College System of Georgia



## Current Limitations

- Space for demonstration facility
  - Composite manufacturing and testing collaboratory
  - Scalable manufacturing systems
- Funding for major research and equipment
  - Both government and industry sponsorships
- Composites-focused core faculty
  - Georgia Tech was regarded as a leader in composites in 1980s-1990s
  - The reputation waned due to retirement and departure of core faculty in composites field
- Strong industry partnership for major projects/ demonstration



## Alpha Test 1



## Summary

- What potential challenges are addressed?
- What are the potential impacts?
- Externally, who requires results and why?
- What internal GT disciplines/organizations are involved/needed
- What external involvement exists/needed?
- What are current limitations?
- Current funding
- Research for achieving challenges

Alpha Test 2

## Manufacturing Challenge Exemplar:

Identify and accelerate research to enable the next level of *global logistics and supply network performance*

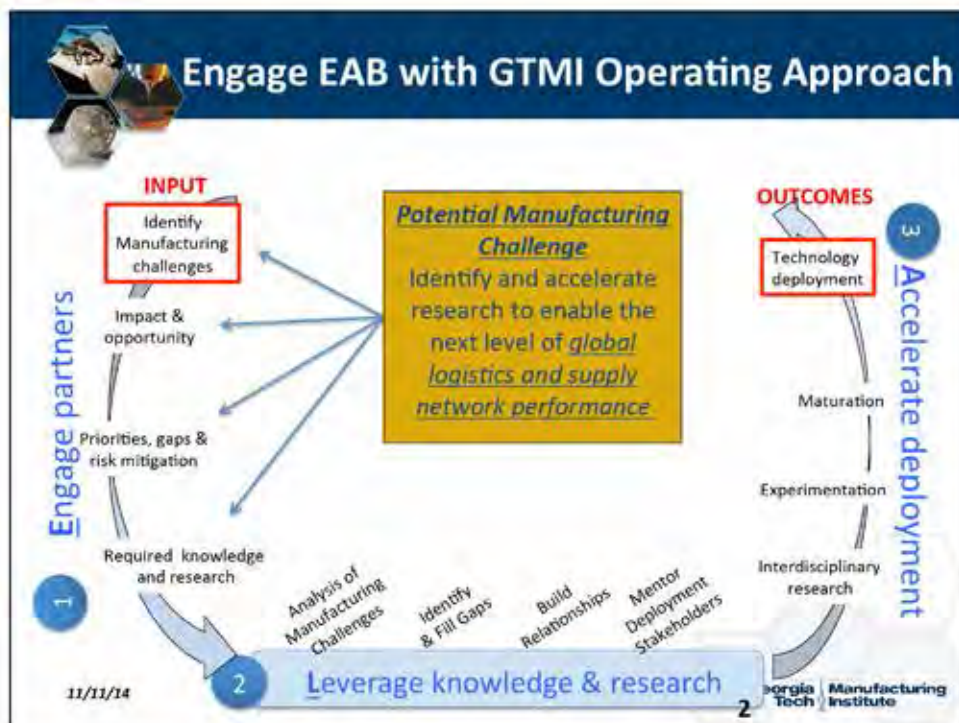


Jennifer Clark, School of Public Policy

Soumen Ghosh, Scheller College of Business

Chip White, School of Industrial & Systems Engineering

12 November 2014



## Alpha Test 2



## Manufacturing in the Global Enterprise Challenges, Opportunities, Impacts

The capability to manufacture products in the global marketplace is being revolutionized by changing:

- *Technologies* – big data, automation, manufacturing innovations
- *Markets & market concentration* - demographics
- *SC design practices & design objectives* – push to pull, Lean + risk
- *Firm & industry structure* – make or buy?
- *Customer demands & service offerings* – eCommerce
- *Public policy & investment* – R&D, innovation, trade, energy

Impacts at all levels: operations, design, strategic, industry, policy



## Big Data Analytics Value of Information (ROIC)

**What are the potential impacts?** A better informed strategic procurement decision-maker; better operational decision-making (6%-12% increases in efficiency)

**Externally, who requires results and why?** The private sector in order to better make procurement and operational decisions

**What internal GT disciplines/organizations are involved/needed?** OM in School of Business, ISyE in COE

**What external involvement exists/needed?** Interaction with firms wanting to know how to better exploit the value in the data collected

**What are current limitations?** A need for mission-driven knowledge discovery. **The gap:** no methodology for easily determining the value of information (or the value of an innovation) for broad classes of applications



## Alpha Test 2



## Global Competitiveness of US Manufacturing Firms

**Past:** Global manufacturing strategy driven predominantly by labor cost arbitrage, but markets and macroeconomic environment now very different

**New Thinking for Manufacturing Capability Development:**

- Labor arbitrage being neutralized by a variety of forces
- Global market fragmentation → Focus is more on fulfilling customer needs
- Increasing consumerization, product variety, and short product lives → focus on speed, responsiveness, & personalization (mass customization)
- Emphasis on manufacturing capability driven by local market access, and proximity to demand and innovation sources
- Next Shoring! (McKinsey Global Inst.) – focus on what's coming *next!*

**Challenges:** Key Words → Responsiveness, Agile, Flexible, Local, Distributed



## Trends in U.S. Manufacturing Policy

**Policy Shift:**

- Taking the *location* of manufacturing Capacity and supply chains seriously - subsequent State, Local, Federal investment
- **Policy Responses:** Manufacturing Policy Initiatives + Policy Processes

**Trends on the Radar:**

- **Realignment of federal strategy** as a response to the AMP 1.0 and AMP 2.0 recommendations
- Significant **state-level** investments *in regional economic ecosystems*
- Collaborative efforts between coalitions of production-networks
- Renewed focus of innovation policy **on enabling technologies** related to **materials and processes** that touch multiple sectors and markets

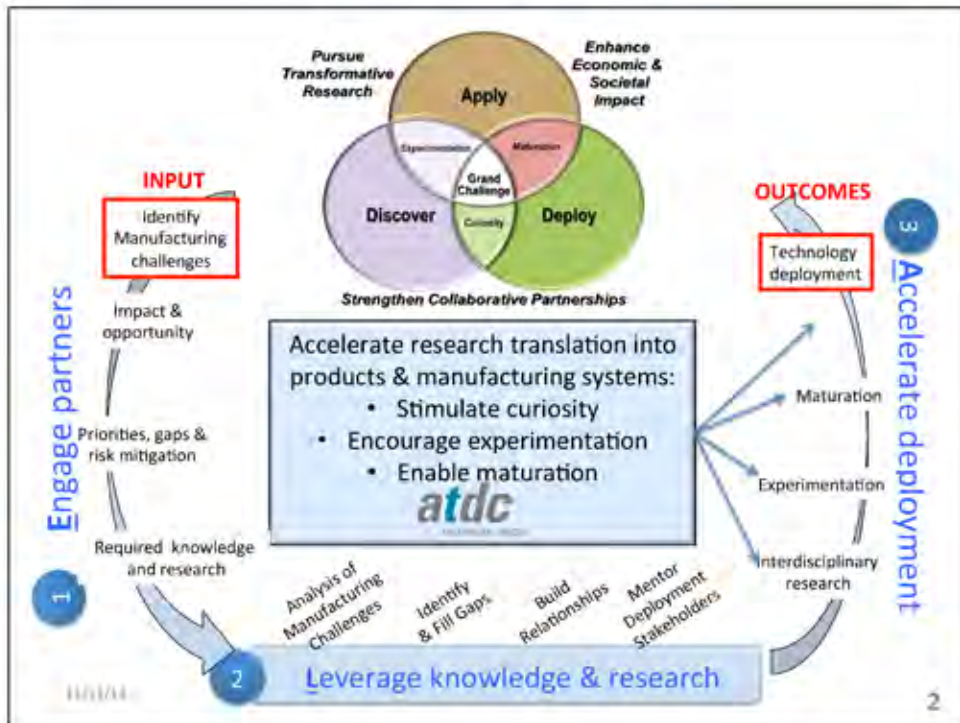
Alpha Test 3



## “Innovation In Incubators and Beyond for Achieving Maturation”

GTMI External Advisory Board (EAB) Meeting  
November 12, 2014

**Chris Downing, P.E.**  
Associate Vice President  
Enterprise Innovation Institute  
Ph. 404-894-7700  
Email: [chris.downing@gatech.edu](mailto:chris.downing@gatech.edu)  
[www.innovate.gatech.edu](http://www.innovate.gatech.edu)





## Alpha Test 3

## Enterprise Innovation Institute - EI<sup>2</sup>

*Leading innovation in commercialization, entrepreneurship and extension services*



**Commercialization**

- Faculty Advising
- Startup formation
- Industry R&D



**2013 Graduates**



**Extension Services**

- Manufacturing
- Healthcare
- Procurement
- Diversity
- Economic Development
- Connection to GT

Accelerate

>

Assist

>

Amplify




## Georgia's Technology Incubator – Managed by Georgia Tech and EI2



**WE HELP ENTREPRENEURS launch and build technology companies in Georgia**



Technology Square Location

- 35 year history of success
- Over 150 Graduate Companies
- 34 Select Member Companies
- Over 500 Entrepreneur Members
- Diverse sectors: healthcare, financial, mobility, etc.
- Strong state funding (over \$2 Million/yr)




Alpha Test 3

**WE HELP ENTREPRENEURS launch and build technology companies in Georgia**



**ATDC Video**

**Dan Ciprari**  
Entrepreneur in Residence - ATDC

<http://player.vimeo.com/video/87800274>








**FORBES TOP 12**

**OUR SERVICES**

Ranked one of the world's top technology incubators and named a Top 12 incubator Changing the World by Forbes in 2013.



**90% SUCCESS RATE**

**OUR SUCCESS**

90% of technology start-ups fail. More than 90% of the ATDC's Select graduates are successful five years after their graduation.



**\$2 BILLION IN CAPITAL**

**OUR PROCESS**

150 graduates have collectively raised more than \$2 billion in capital. In 2013, seed companies mentored \$50+ million in capital.




Alpha Test 3

Some of the Manufacturing/Product-Based Companies at ATDC

lumense



nextinput

Predikto

SENSIOTEC



SoftWear

SONETER

Startup Success



Acquired by



ST. JUDE MEDICAL



Translational Success

- GT research
- GT VentureLab formed company
- GT ATDC startup company
- Manufacturing in a GT Research Park (TEP)





Alpha Test 3

**Recent ATDC Incubator Innovations and Initiatives**

- **Industry Connect Program**  
*Connecting Fortune 1000 with ATDC startups - 20 contracts and more than \$3.4 million in payments and investments since 2013.*
- **Design Studio / Makers Space within ATDC**
- **MEP funds to support manufacturing related research contracts** *(in conjunction with DEcD Innovation Center funding)*
- **Embedding incubation space within GT Research Centers**



**Supporting GT's Next Innovation Neighborhood**



Opportunity to create a mixed used development to include urban manufacturing space



## Alpha Test 3

**Current Limitations and Needs**

- Manufacturing startup support limited by state funding *(diversification with corporate and foundation funding)*
- Shared manufacturing space *(improved access to high cost test and process equipment)*
- More diverse incubation space *(lab-space, light manufacturing, co-working)*
- Expansion of Research Parks around campus *(for corporate innovation centers and incubator graduates)*
- Venture Fund for product-based companies

Georgia  
TechEntrepreneurial  
Innovation  
Institute**Discussion on Incubator Innovation**atdc  
ATLANTA TECH DEVELOPMENT CENTER

ATDC is addressing the challenge to translate research into products & manufacturing systems.

An opportunity exists to significantly expand our incubation services and impact through partnerships with internal and external partners.

Some questions to consider:

*Are ATDC's current strategies such as "Industry Connect", "design studio" and "embedded incubation space" the right direction?*

*How should GTMI and ATDC pursue a joint strategy for a "Manufacturing Innovation Neighborhood at GT"?*

*What features of our research parks could help enhance and expand incubation activity?*

*What other sources of funding for incubation services and funding startups have we not considered?*

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TechEntrepreneurial  
Innovation  
Institute

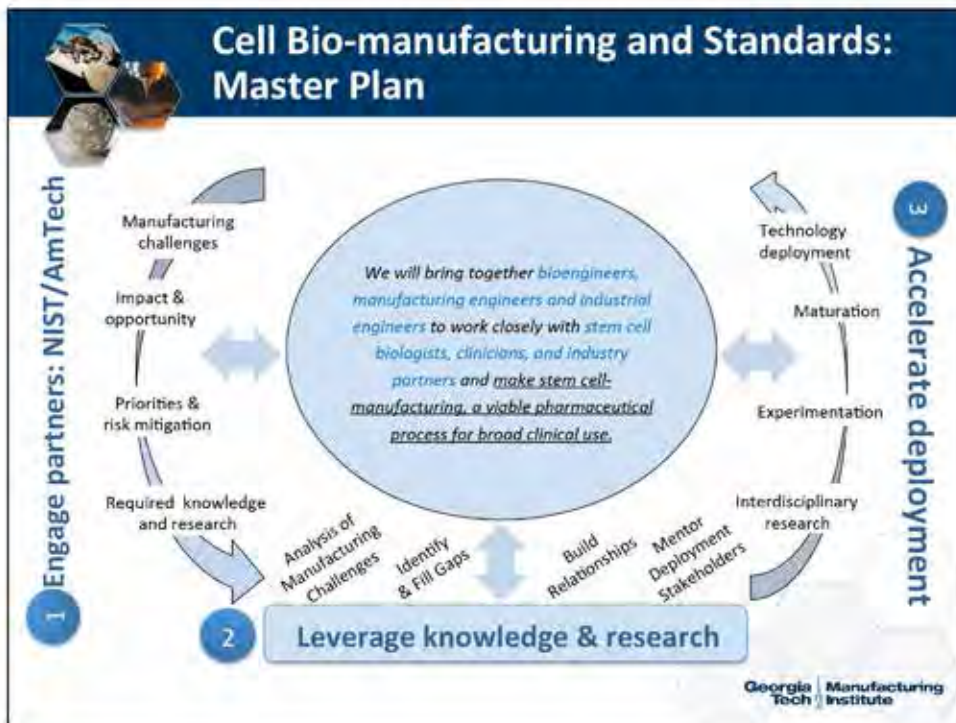
Alpha Test 4

**Manufacturing Challenge Exemplar:**

**Cell Bio-Manufacturing and Standards**  
 Transforming cell therapies into viable pharmaceutical products

**Krishnendu Roy, PhD**  
 Carol Ann and David D. Flanagan Professor  
 Director, Center for ImmunoEngineering  
 The Wallace H. Coulter Department of Biomedical Engineering and  
 The Parker H. Petit Institute for Bioengineering and Bioscience

November 12, 2014

Alpha Test 4

## Stem Cell Therapy: Clinical Impact Areas

Altherys (Phase II)	Ischemic Stroke	Blindness	Cell Cure Neurosciences
Neurogeneration (Preclinical)	Traumatic brain injury	Diabetes	Living Cell Technologies (preclinical)
Neurogeneration (Preclinical)	Alzheimer's disease	Gingival gum degeneration	IntellCell BioSciences
Neurogeneration (Phase II)	Parkinson's disease	Amyotrophic lateral sclerosis	BrainStorm Cell Therapeutics
BrainStorm Cell Therapeutics	Huntington's disease	Ischemic heart failure	Cardio 3 BioSciences (Phase II)
Living Cell Technologies (Preclinical)	Huntington's disease	Myocardial infarction	Altherys (Phase II)
Opeks Therapeutics (Phase II)	Multiple sclerosis	Peripheral artery disease	Cook MyoSite (Phase III)
IntellCell BioSciences	Wound Healing	Hematological malignancies	Cytos Therapeutics (Phase I/II)
Soluble Systems (commercial)	Wound Healing	Diabetes	Pluristem Therapeutics
Promethera BioSciences (Phase I/II)	Liver disease	Acute kidney injury	Quinida Cell
Neurogeneration (Preclinical)	Spinal cord injury	Urinary incontinence	Living Cell Technologies (Phase III)
Regeneva (Phase I)	Spinal cord injury	Fecal incontinence	AlloCure (Phase II)
ISTO Technologies (Phase II)	Spinal disc regeneration		Cook MyoSite (Phase II)
IntellCell BioSciences	Osteoarthritis		Innovacell Biotechnology (Phase III)
Altherys (Phase I)	Inflammatory bowel disease		Cook MyoSite (Phase III)
			Innovacell Biotechnology (preclinical)

Courtesy of Feldan Inc

ecm institute

## Stem Cell Therapies and Regenerative Medicine: The Market

### RM Market : Key Metrics

**Rapidly Expanding Market:**

- \$3.8B in 2011; \$6.6B in 2016
- \$20.0B in 2025
- CAGR of 12.6%

**Dramatic Revenue Growth**

- \$130M in 2001
- \$2.0B+ in 2013

**Increased Funding in 2013: \$4.7B+**

- VC, PIPEs, IPOs, Partnerships

**Clinical Programs**

- 4400+ Clinical Trials
- 2800+ "New" RM Technologies
- 560+ in Late Stage (P3/PIV)

**Commercial Products**

- 2,500+ on Market (Mostly Skin, Tools Media, & Devices)
- 40+ Cell Therapies on Market
- \$900M+ in Revenues

**1.2M+ Patients Treated with RM Products.**

- 320K+ Cell Therapy Patients

**RM Companies**

- 700+ Co's involved in RM
- 80+ Public "Pure" RM Co.'s
- \$12.4+B Total Market Cap
- 300+ Private "Pure" RM Co.'s

CONFIDENTIAL | 3

PROTEUS

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## Alpha Test 4



## While the promise is clear ...

- **Stem cell therapy remains a 'mom and pop' operation restricted to clinicians and hospitals**
- **There are NO standard operating practices or commonly agreed standards for QA/QC**
  - Even small differences in processing can lead to large difference in cell-activity and clinical outcome
  - Very few methods standardized and cross-validated methods are available for
    - Cell (raw material) expansion
    - Cell characterization (QA/QC)
    - Scale up or scale out
- **The question is: WHY and what can WE at Georgia Tech do about this?**



## Stem Cell Therapy Industry Challenges

- **Regulatory environment:** improve clarity and predictability
- **Process development & manufacturing** – ability to scale up
- Lack of **standards and product characterization**
  - release criteria, cell identification, safety, potency
- **Reimbursement:** Improved clarity and consistency
- **The transformative potential of regenerative medicine on medical care will only be realized when stem cells can be manufactured as a low cost, well characterized, highly reproducible, and scalable commodity**

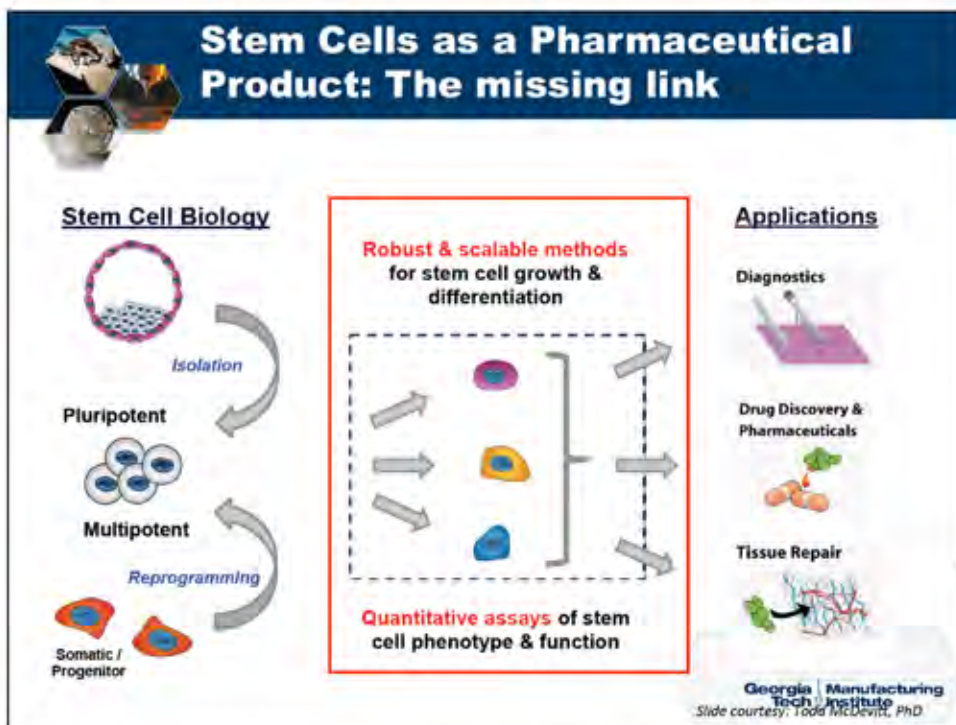
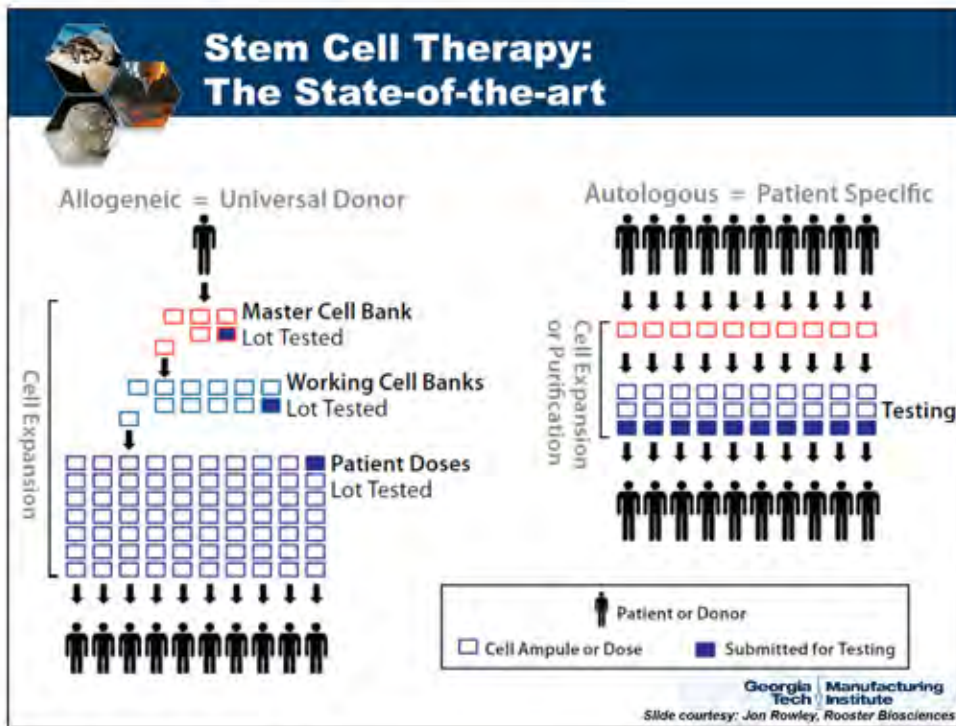


Scale-up

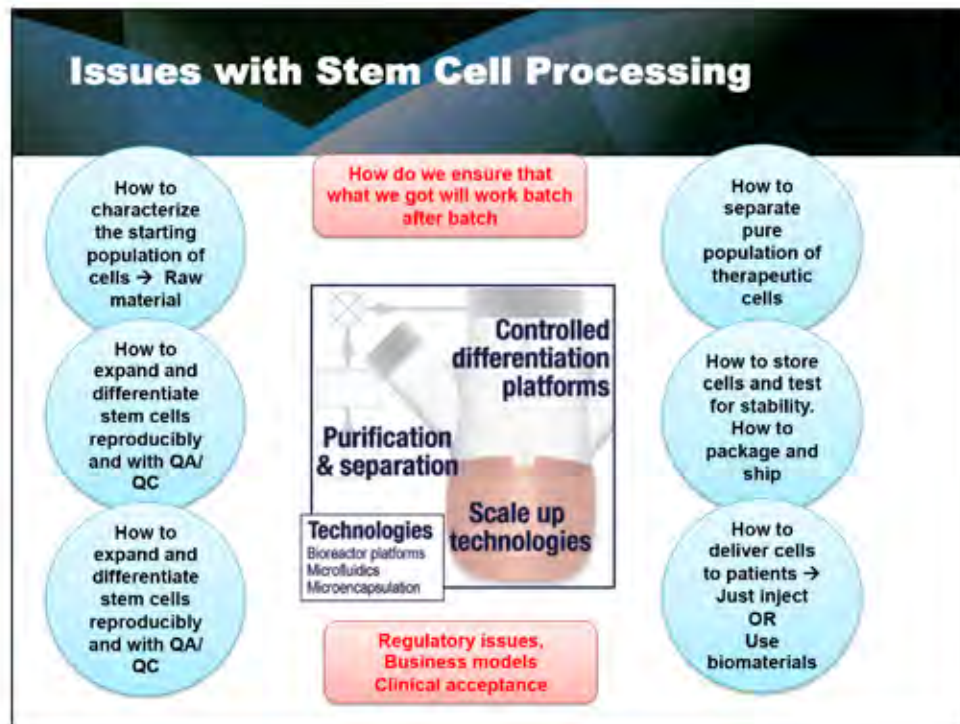




Alpha Test 4



## Alpha Test 4

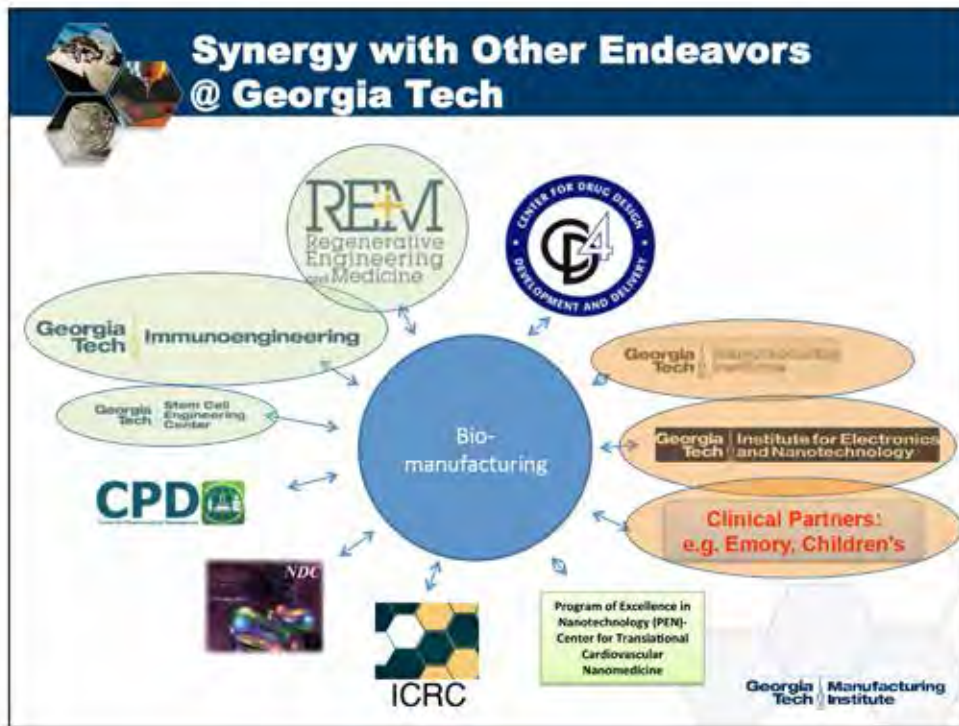


## What technological advances are needed?

- Develop new tools for **cell characterization** both at the starting point and throughout the process → **QA/QC**
- Develop new tools for **scale-up and scale-out** of both raw materials (starting cells) and product (differentiated cells) → **Materials, Bioreactors, Microfluidics, Assays**
- Develop technologies for **cell purification, separation, delivery, packaging and storage** → **Microfluidics, Biomaterials, QA/QC**
- Incorporate **industrial design principles, automated robotics-based systems** and manufacturing processes
- Translate our **engineering methodologies and new technologies** to **pre-clinical and clinical applications** in collaboration with clinicians and industry → **GMP facility**

Georgia Tech Manufacturing Institute

Alpha Test 4



### Georgia Tech: Innovative approaches in cell therapy

**Adhesion strength-based, label-free isolation of human pluripotent stem cells**

Adnan Singh<sup>1,2</sup>, Marko Vucelja<sup>1,2</sup>, Ted Lee<sup>1</sup>, James M. Collins<sup>1</sup>, Marissa T. Cowley<sup>1</sup>, Pengkang Chen<sup>1</sup>, Weiping Ren<sup>1</sup>, Steven S. Wang<sup>1</sup>, Hong Lu<sup>1</sup>, Todd C. McDevitt<sup>1,2</sup> & Nathan F. Schaefer<sup>1,2</sup>

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## Alpha Test 4

## Georgia Tech: Innovative approaches in cell therapy





**The New York Times**  
In Girl's Last Hope, Altered Immune Cells Beat Leukemia  
By DENISE GRADY  
December 9, 2012



**STEM CELLS**  
Tissue-Specific Stem Cells  
Generation of Functional, Antigen-Specific CD8<sup>+</sup> Human T Cells from Cord Blood Stem Cells Using Exogenous Notch and Tetramer-TCR Signaling  
Jesse Andrews<sup>1,2</sup>, Tracy P. Day<sup>1,2</sup>, Elizabeth Bar<sup>1</sup>

Georgia Tech Manufacturing Institute

## Georgia is leading the Roadmap Initiative for the United States

**The Advanced Manufacturing Technology Consortia (AMTech) Program**

- **Launched by NIST in FY 2013**
  - To incentivize the formation of and provide resources to industry-driven consortia
    - To support basic and applied research
    - On long-term, pre-competitive and enabling technology development
- **Nineteen (19) Awards**, totaling \$9 million
- **We are the ONLY one in the BIO area**



Georgia Tech Manufacturing Institute



## Alpha Test 4



## Cell Manufacturing Consortium

The CMC is led by the Georgia Research Alliance (GRA) and Georgia Tech. It is initially composed of five universities and four companies engaged in cell manufacturing.

- Create a national consortium for stakeholders involved in cell manufacturing.
- Bring industry and academia to identify barriers impeding progress of cell manufacturing technologies.
- Bring industry and academia to identify future research directions.

Project Number: 70NANE14HQ48  
 NIST Funding: **\$499,636**  
 Project Period: June 2014 to Nov 2015  
 Technical Lead: Krishnendu Roy  
 404-385-6166  
[krish\\_roy@gatech.edu](mailto:krish_roy@gatech.edu)  
 Project POC: Greg Dane (GRA)  
 678-925-7576  
[gdane@gra.org](mailto:gdane@gra.org)

### Project Events

- Series of workshops (First one on Dec 1, 2014 in Atlanta) – invited speakers & attendees → Leading to Roadmap development for the United States

### Project Deliverables

- A roadmap for technological innovations involving stakeholders of the entire cell manufacturing value chain
- Acceleration of cell-derived products to the healthcare market.

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## To summarize...

- The obvious potential of stem cell therapies is well known → Both commercial and human health
- **It is not a viable 'product' yet due to manufacturing capability and QA/QC shortcomings**
- Georgia Tech has the expertise and the know-how to bring together scientific, industry and clinical teams to develop new assays, scale up technologies and transfer these to clinical partners
- **GT has committed to do this initiative** – GTMI must play a key role in this national priority

Georgia Tech | Manufacturing Institute

## Alpha Test 4



## To summarize ...

- **What Potential Manufacturing Challenge is Addressed?**
  - *Biological Cell-Manufacturing Technologies and Standards*
- **What is the impact?**
  - *Transformative change that will bring stem cell therapies to all patients*
  - *Lead to better outcome of clinical trials and therapies by defining standards, best practices, scale up and scale out processes and QA/QC*
- **Externally, Who Requires Results and Why?**
  - *Currently - NIST National Manufacturing Initiative on "Consortiums Addressing Issues Hampering US Advanced Manufacturing"*
  - *Cell Therapy and Regenerative Medicine industry; Clinicians*
- **What Internal GT Disciplines/Organizations are Involved/Needed?**
  - *BME, ME, ChBE, EE, MSE, ISYE, Biology, Chemistry and Biochemistry*
  - *IBB, GTMI, Robotics, IEN*
- **What External Involvement Exists/Needed?**
  - *Georgia Research Alliance (GRA), Emory, Duke, NIST*
- **What are Current Limitations?**
  - *Current Funding - Limited to Road-mapping (\$499K and 18 months) Future Project funding based on consortium investments and plans.*
  - *Research for Achieving Challenges - Discussed in detail*
  - *Other - Lack of standards; need broad end user buy in.*

**Discussion & Feedback**

**1. Is GTMI on the right track for GTMI strategy and execution?**

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**2. Has GTMI captured the roles and skills scope of the EAB going forward?**

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**3. EAB perspectives on formalizing a GTMI-EAB-IAB methodology identifying GTMI Manufacturing Challenges and entire "Engage Partners process"?**

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**4. EAB proposed topics for the Spring 2015 EAB?**

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