



ManufacturingUSA<sup>SM</sup>

# The National Network for Manufacturing Innovation Briefing for the 2017 ASEE Public Policy Colloquium

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An interagency team building partnerships with U.S. Industry and Academia



2017 Engineering Deans

**Public Policy Colloquium**

Fairmont Hotel • Washington, DC • February 6-8, 2017

# Engineering and the 115<sup>th</sup> Congress

**Many issues today involve science and technology**

***ASEE Engineering Congressional input is critical to sound policy***

**Of the 535 Members of the 115<sup>th</sup> Congress, 2% (13) have engineering expertise**

Senator Steve Daines (R-MT) - B.S. chemical engineering 1984

Senator Martin Heinrich (D-NM) - B.S. mechanical engineering 1995

Rep. Joe Barton (R-TX) - B.S. industrial engineering 1972

Rep. Tony Cárdenas (D-CA) - B.S. electrical engineering 1986

Rep. Chris Collins (R-NY) - B.S. mechanical engineering 1972

Rep. Joseph Kennedy, III (D-MA) - B.S. management science & engr. 2003

Rep. Raja Krishnamoorthi (D-IL) - B.S. mechanical & aerospace engr. 1991

Rep. Daniel Lipinski (D-IL) - B.S. mechanical engineering 1988

Rep. Thomas Massie (R-KY) - S.M. mechanical engineering 1996

Rep. David McKinley (R-WV) - B.S. civil engineering 1969

Rep. Brad Schneider (D-IL) - B.S. industrial engineering 1983

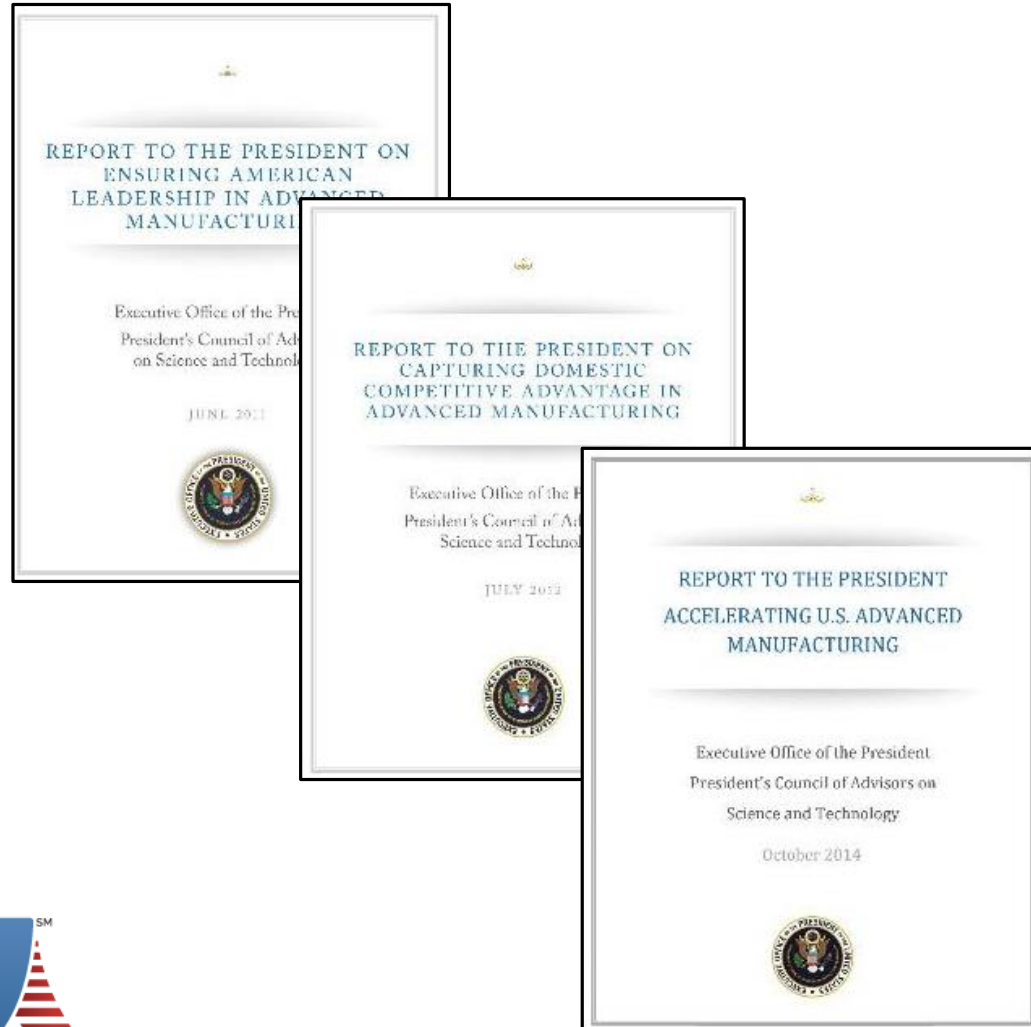
Rep. Paul Tonko (D-NY) - B.S. mechanical & industrial engineering 1971

Rep. Bruce Westerman (R-AR) - B.S. biological & agricultural engr. 1990

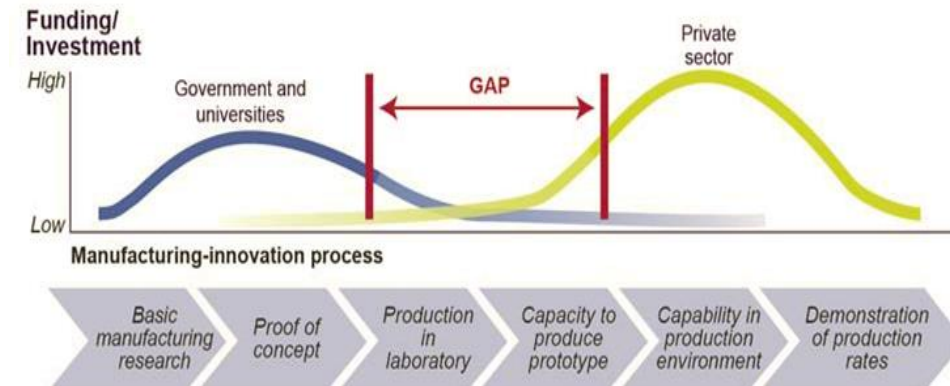


# Manufacturing USA addresses national need

## President's Council of Advisors on Science and Technology



## Market Failure in Pre-Competitive Applied Manufacturing R&D



National Network for Manufacturing Innovation creates the space for industry and academia to work on industry-relevant problems

- Addresses the market failure of industry underinvestment in “pre-competitive” applied R&D
- Focuses on “de-risking” new technologies and materials to scale-up for U.S. manufacturers



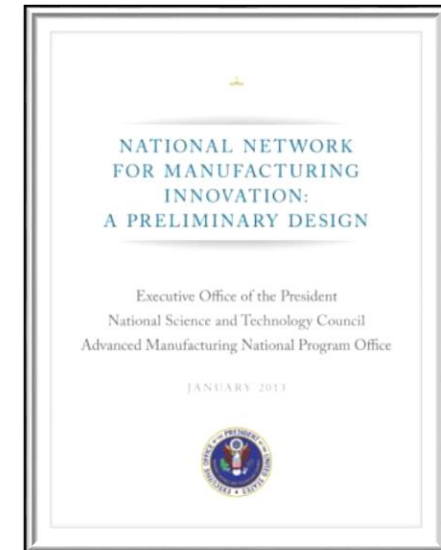
# Manufacturing Institute Framework

**Applied Research + Education/Workforce Skills =  
Development of Future “Manufacturing Hubs”**

- Federal funding is the **catalyst** to bring stakeholders into shared space to de-risk innovation.
- Focus is on **industry-relevant problems** impacting commercial production, MRL 4-7.
- Institutes must be **self-sustaining** after federal startup investment ends.
- **Workforce training and development** is an essential component in institute focus.



White House Report  
Framework Design  
January 2013

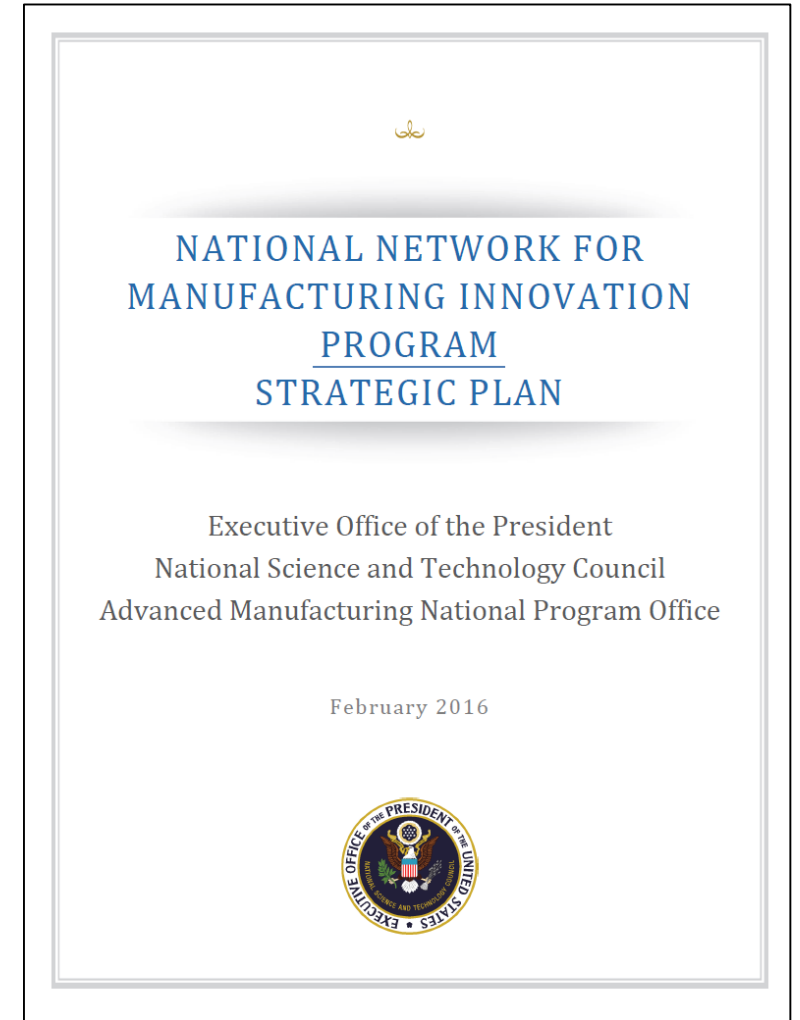


Federal startup investment: \$70M - \$120M/institute over 5 years  
Institute Consortium owners must have minimum 1:1 co-investment

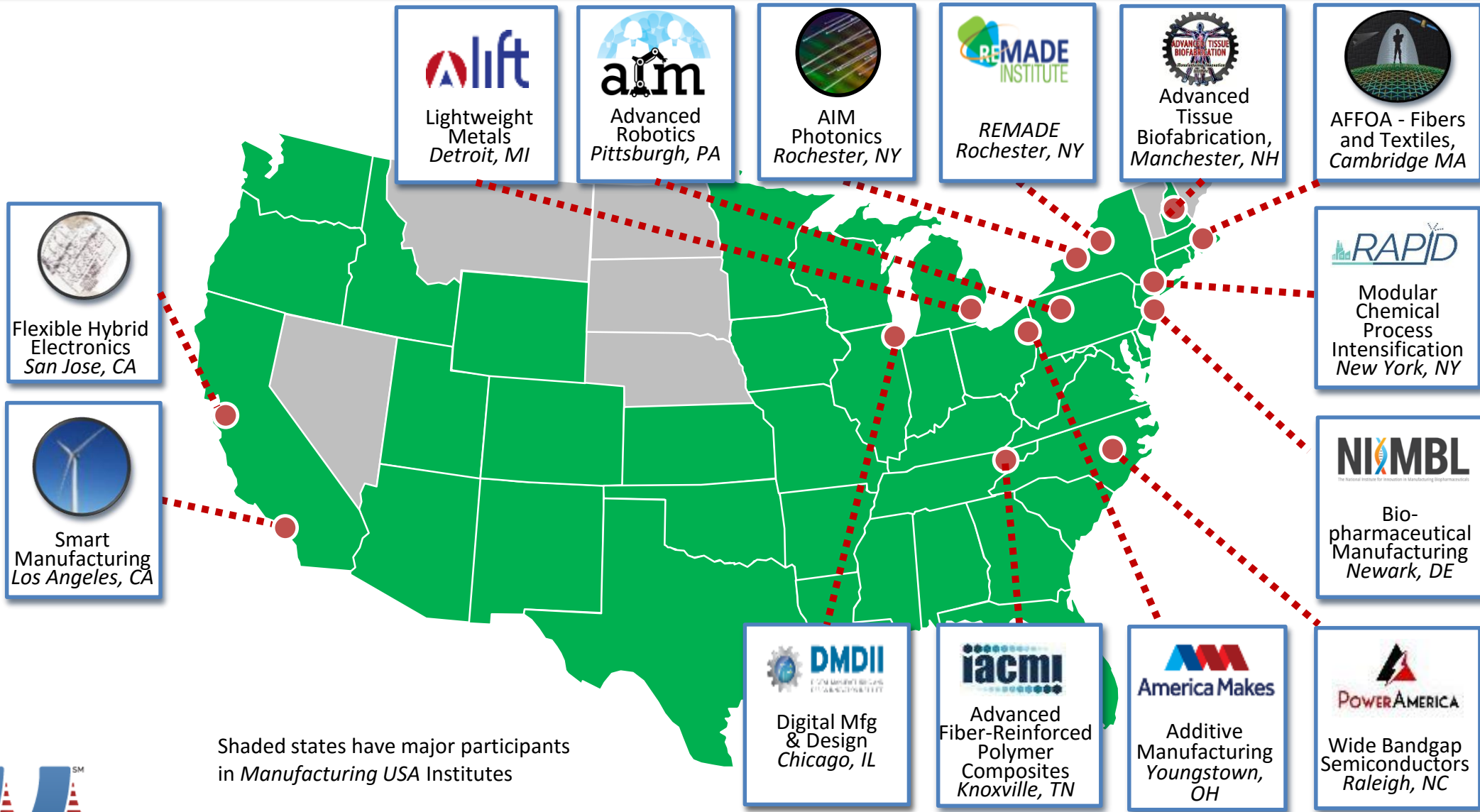


# Manufacturing USA Strategic Goals

- Increase the competitiveness of U.S. manufacturing.
- Facilitate the transition of innovative technologies into scalable, cost-effective, and high-performing domestic manufacturing capabilities.
- Accelerate the development of an advanced manufacturing workforce.
- Support business models that help institutes become stable and sustainable.



# Manufacturing USA Today



Shaded states have major participants in Manufacturing USA Institutes



# Example Institute: NIIMBL

# NIIMBL

The National Institute for Innovation in Manufacturing Biopharmaceuticals

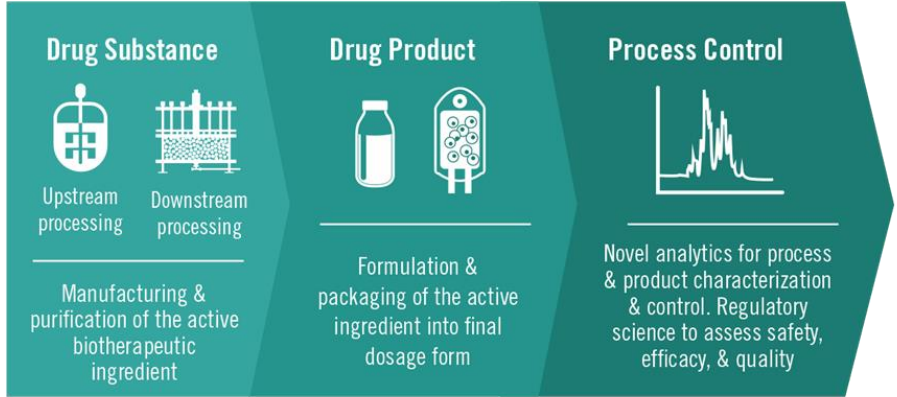
**NIST**  
**National Institute of  
Standards and Technology**  
U.S. Department of Commerce



**140+  
Partners**  
A public-private  
partnership of industry,  
academic, non-profits  
and government entities.



# NIIMBL



# *1) Each Institute has a clear mission based on a critical Industry need*

## Our Mission

The NIIMBL mission is to accelerate biopharmaceutical manufacturing innovation, support the development of standards that enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce, fundamentally advancing U.S. competitiveness in this industry.





## 2) *Each Institute creates value for industry participation and funding*



A place where industry, academic, state, and U.S. federal resources synergize to

- meet industry's needs
- de-risk and streamline process development
- train a growing workforce spanning the full supply chain

- Regulatory advancement is streamlined
- Enhanced process robustness is obtained
- Major manufacturers work with suppliers to develop new technologies
- Standardization of interfaces, assays, parts, and certifications is achieved
- New methods, technologies, and best practices are achieved collaboratively with health authorities
- Workforce creation matches industry needs

**NIAMBL**

AMERICAN INNOVATION AT WORK

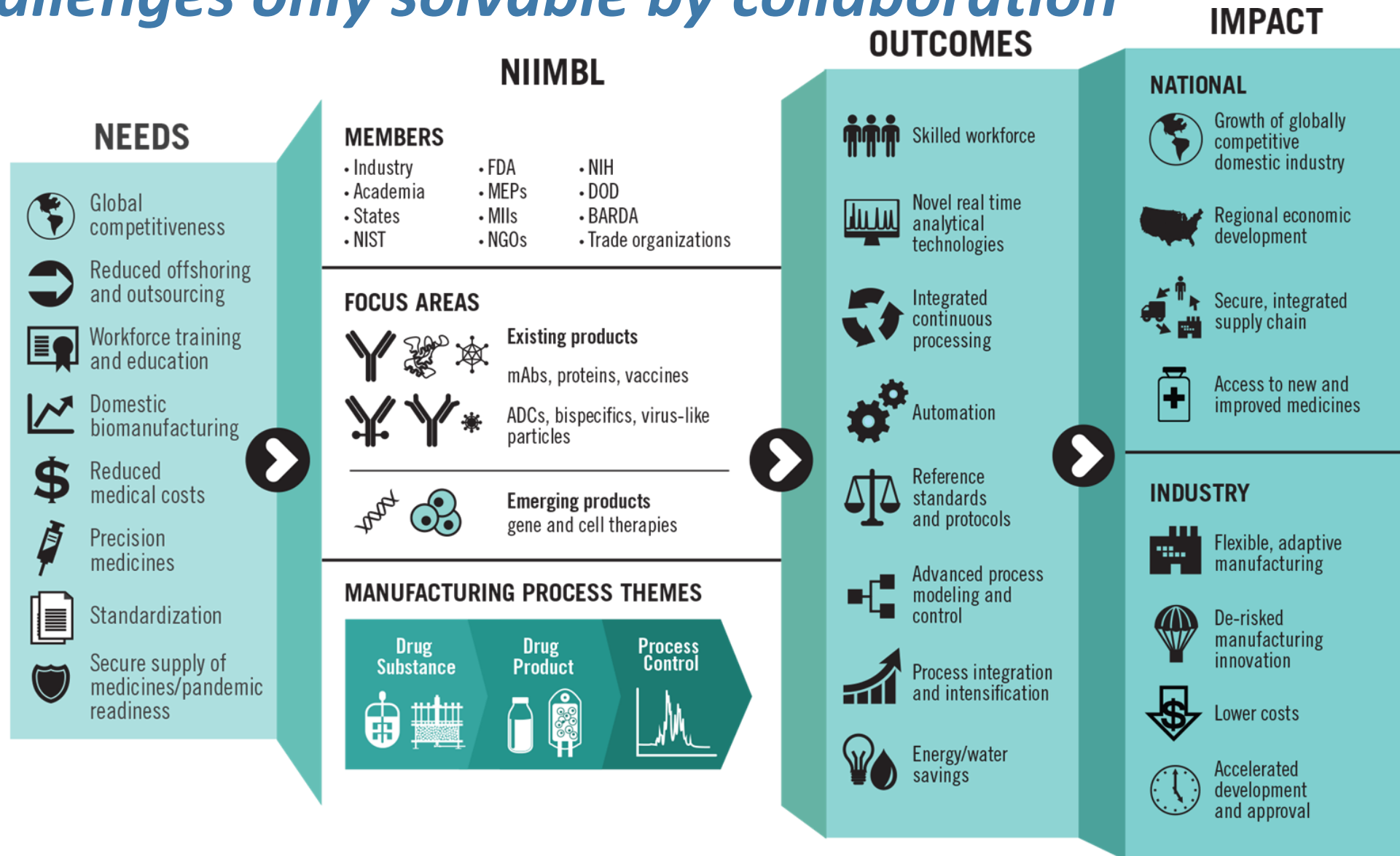
### 3) Each Institute is operated by an industry-led consortium

*NIIMBL: national impact with shared resources in West, Midwest, Southeast, Mid-Atlantic, and Northeast regional hubs, operated by USA Bio LLC*

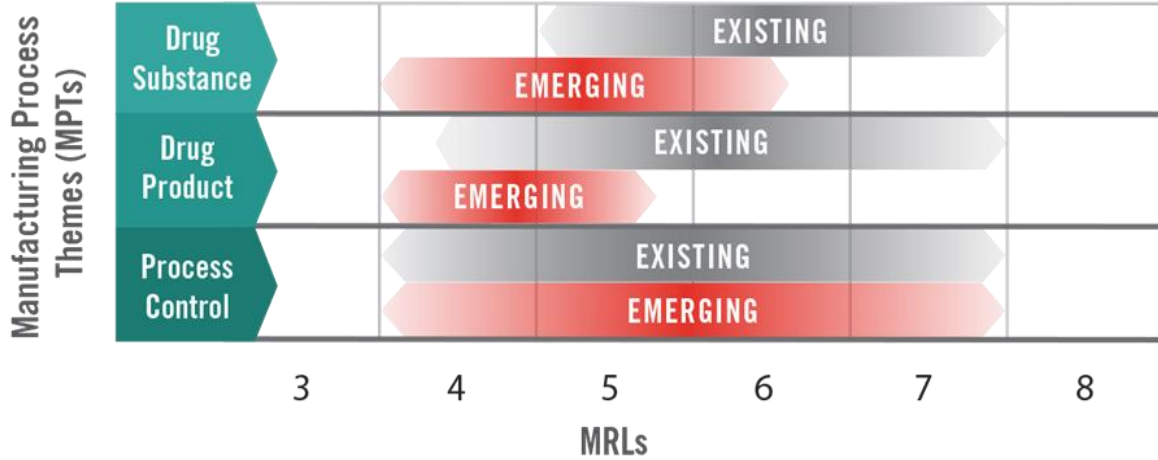


- NIIMBL Members span the entire biopharmaceutical manufacturing ecosystem
- 150 members pending at launch:
  - 103 companies, trade groups, and non-profits
  - 41 academic partners
- 25 states represented in NIIMBL consortium

# 4) Each Institute works on the industry priorities and big challenges only solvable by collaboration



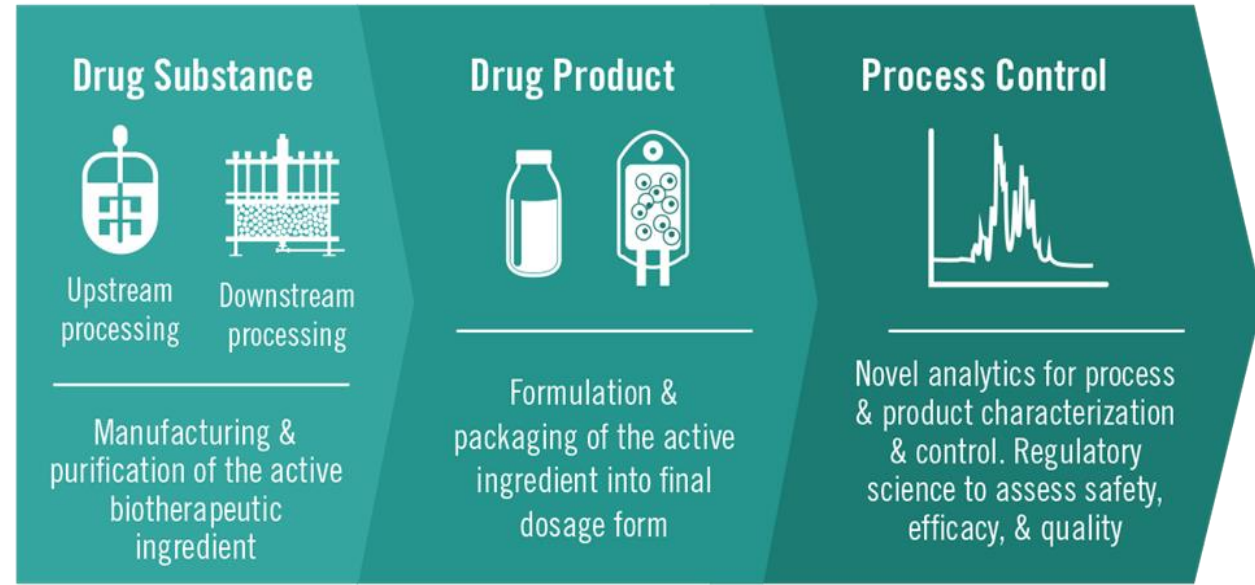
# 5) Each Institute manages a balanced portfolio of real projects for industry



**Product Focus Areas (PFAs)**

- Existing Products (*mAbs, vaccines, ADCs, bispecifics, etc.*)
- Emerging Products (*gene therapies, cell therapies, etc.*)

## Manufacturing Process Themes



- NIIMBL plans two project calls per year in ongoing operations,.
- ‘Quick Start’ project calls will be issued at close of the start-up phase.
- A regulatory coordination committee may issue special project calls at any time.

# Third Party Assessment Commissioned

Deloitte studied key areas in order to evaluate and assess Manufacturing USA's national-level impacts, including:

- Program Theory and Structure

- Is the program doing the right things?
- Is the program meeting objectives / impacts?

- Program progress

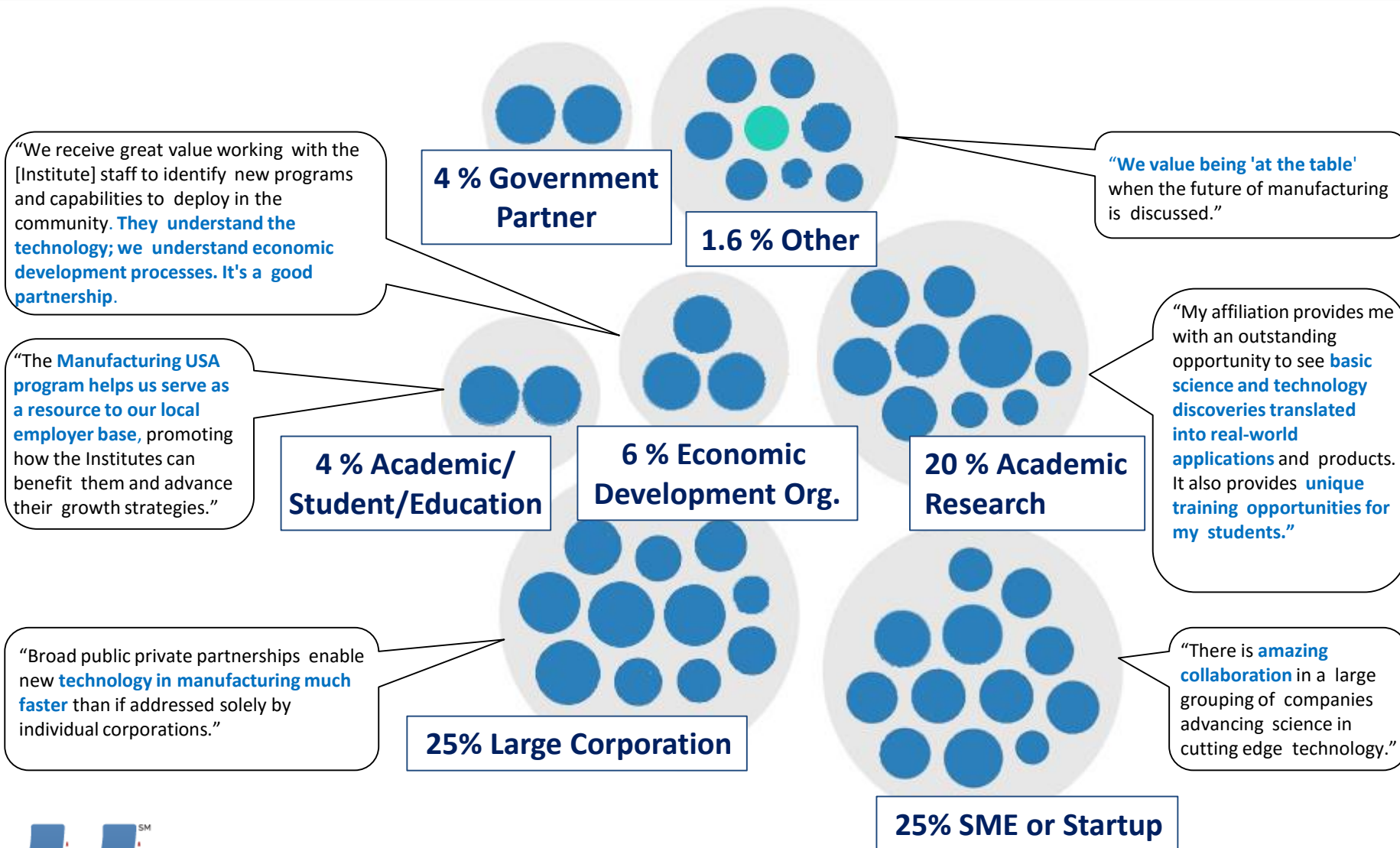
- How is the program performing, achieving its objectives, and creating impact?
- Qualitatively, what are case studies / examples of impact?
- Quantitatively, what does the data tell us about impact?

- Recommendations

- What can be improved?



# Extensive Research and Evaluation



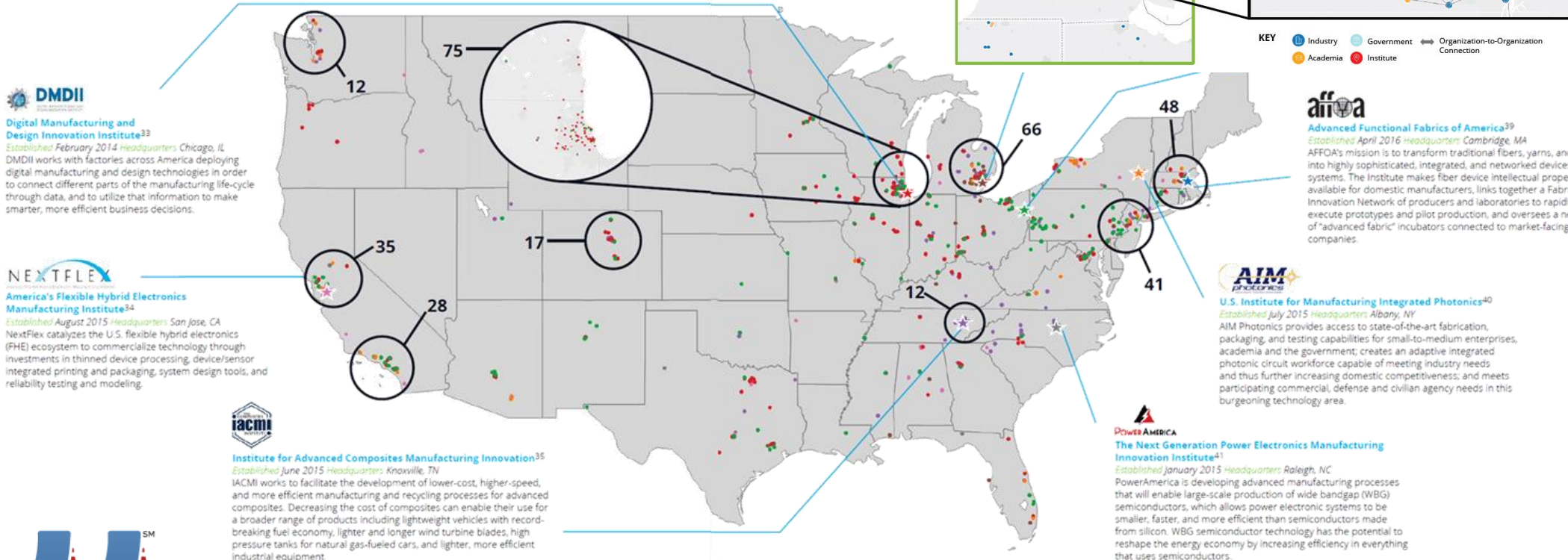
- Deloitte conducted:
- Extensive interviews
  - Site visits to all the institutes
  - Review of institute data
  - Research on comparable international efforts

More than 200 institute and program stakeholders were engaged in a crowd discussion to generate powerful insights in support of study findings



# Formation of Regional Clusters

Manufacturing USA shows signs of strengthening regional economic clusters



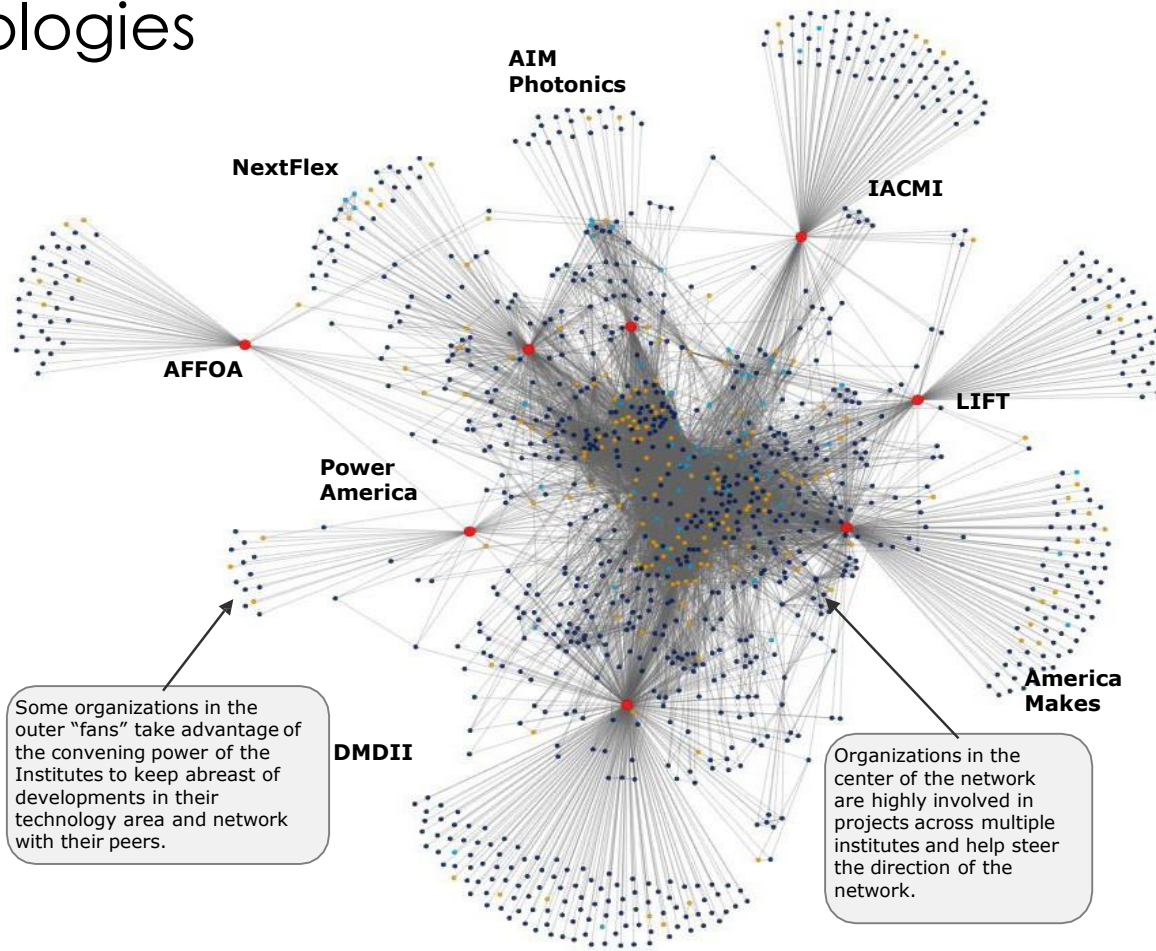
**Inset:**  
Advanced Manufacturing Ecosystem in Detroit, MI – Anchored by the LIFT Institute

**63** organizations from across **seven Institutes** have generated **125 connections**



# The Power of Connections

Manufacturing USA Institutes address the “valley of death” through seed funding and by bringing together stakeholders to commercialize advanced technologies



Together, the Institutes’ convene **nearly 1,200 organizations** in an inter-industry network comprised of **9,000+ organization relationships**





# Collaboration Multiplier Effect

- Institutes decrease the cost of experimentation for their members by providing access to cost prohibitive equipment and pooling R&D dollars.
  - Institutes are demonstrating the potential to deliver 5x leveraged value for members
  - Institutes give members access to not only government funding and partner funding on projects but also broader IP portfolios and R&D



PowerAmerica Institute member facility.



DMDII Facility in Chicago, Illinois



# Third Party Assessment Findings & Program Progress

## Key Findings - Manufacturing USA Spurs R&D Innovation

- The Program is a highly effective ecosystem convener
- Institutes are demonstrating the potential to deliver 5x leveraged value for members
- Institutes are successfully planning for sustainability independent of U.S. government influence

## Progress to Date

- As of today, 14 institutes launched - \$1 billion federal investment matched by over \$2 billion non-federal
- Of Eight active institutes: 1,300 members, over 240 technology development projects.
  - Members include two-thirds of Fortune 50 U.S. manufacturers
  - 8 out of the 10 top-ranked research and engineering universities.



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Thank You!

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