

Today's sessions will be recorded
for note taking purposes

MPWRM Resource Center 2nd Annual Stakeholder's Summit

5 September 2019



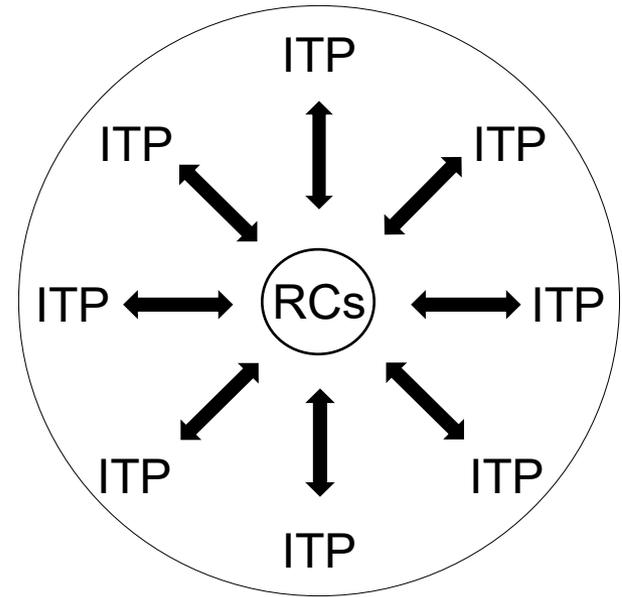
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WELCOME



NIDCR Expert Panel

Industry Partners



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MEETING AT A GLANCE

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Sept 5 (Th) Resource Center and Operating Committee Meetings and Partnering Forums

- 7:30 am Welcome Remarks
- 8:00 am ITP Presentations
- 11:00 am Practicum Session 1: Commercialization
- 11:45 am Lunch
- 1:00 pm Practicum Session 2: Regulatory
- 1:45 pm Open Session Adjourns
- 2:00 pm CLOSED DOOR SESSIONS
- ITP Progress Presentations
- Partnering Forums
- Operating Committee Discussions

ITP Progress Presentations	Partnering Forums	
ITP Teams	ITP Teams	ITP Teams
Operating Committee Advisory Team	MPWRM RC Experts	Industry Partners
NIDCR Program Directors & Expert Panel	Advisory Team	
C-DOCTOR MPWRM RC personnel		

Sept 6 (F) Operating Committee Meetings and Partnering Forums

- 8:00 am CLOSED DOOR SESSIONS
- ITP Progress Presentations
- Partnering Forums
- Operating Committee Discussions
- 12:00 pm Working Lunch
- 1:30 pm Meeting Adjourns



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OVERVIEW

State of the MPWRM Resource Center

Progress on Aims of Resource Center (Stage 2)

- Current ITP demographics

Updates since January 2019

- Stage 3 proposal submitted!

Looking Ahead to Stage 3



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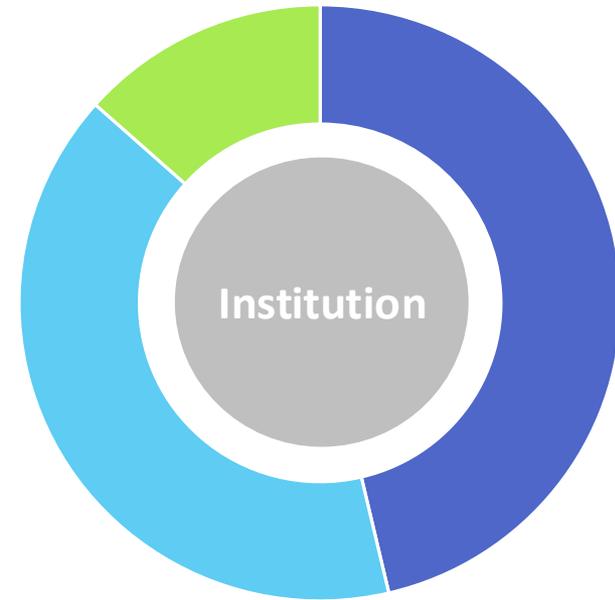
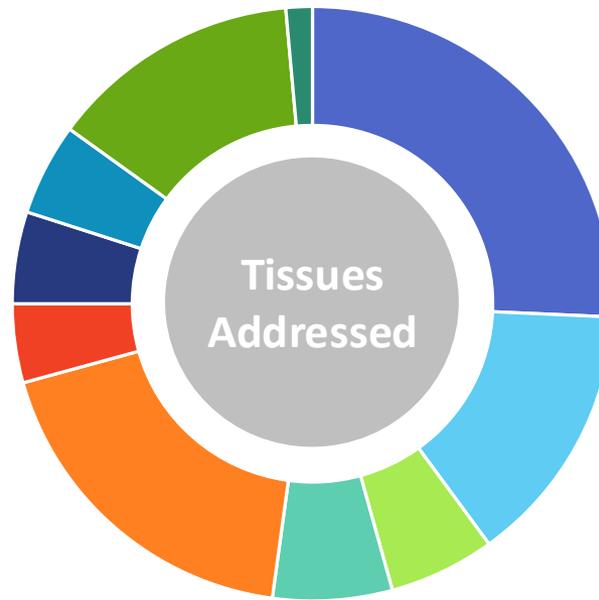
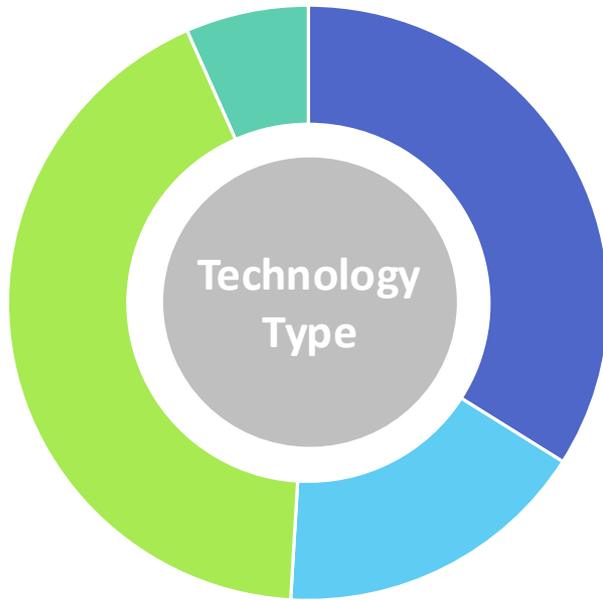
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PROJECTS REVIEWED IN CYCLES 1-3

Application demographics (n=82)



- Biologic
- Cellular
- Device
- Drug

- Bone
- Dental implant
- Muscle
- Nerve
- Periodontal
- Salivary gland
- Skin
- TMJ
- Tooth
- Other

- Internal
- External
- External: for-profit



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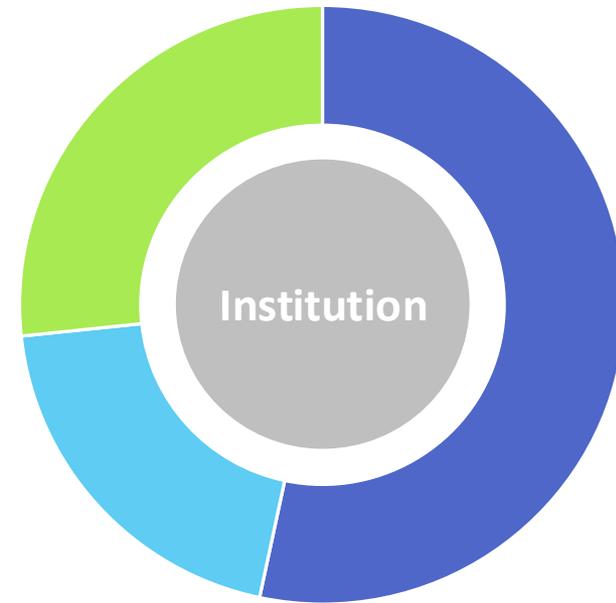
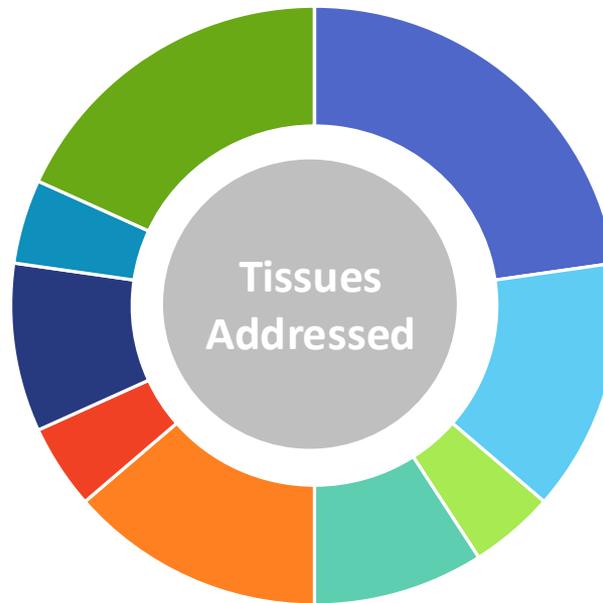
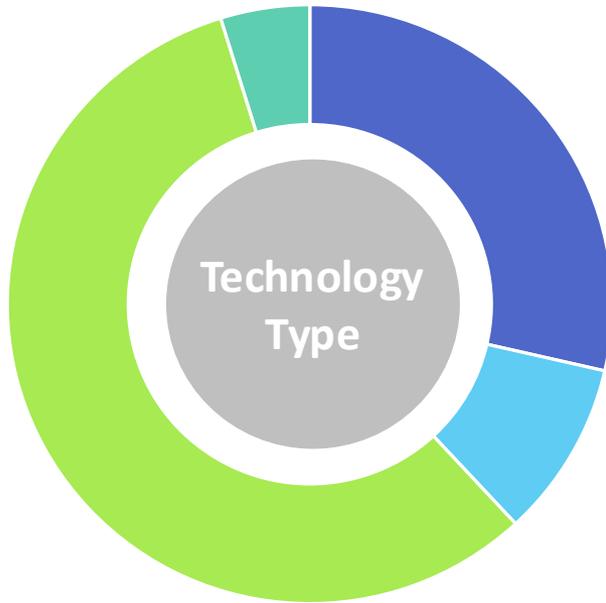
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CYCLE 1-3 CURRENTLY ACTIVE ITPs

Awardee demographics (n=15)



- Biologic (Blue)
- Cellular (Light Blue)
- Device (Green)
- Drug (Teal)

Most products for in-office (vs hospital) use

- Bone (Blue)
- Dental implant (Light Blue)
- Muscle (Green)
- Nerve (Teal)
- Periodontal (Orange)
- Salivary gland (Red)
- Skin (Dark Blue)
- TMJ (Dark Teal)
- Tooth (Dark Green)
- Other (Dark Teal)

- Internal (Blue)
- External (Light Blue)
- External: for-profit (Green)

To learn more about the projects, please visit <https://doctrc.pitt.edu/funded-itp-projects/>



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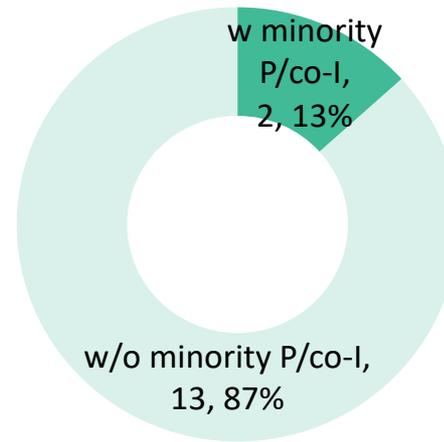
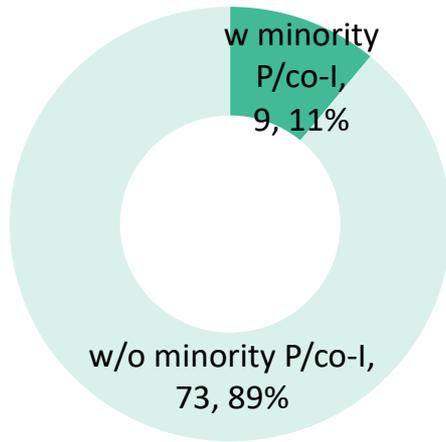
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MIND THE GAP...

Application demographics (n=82) → Awardee demographics (n=15)

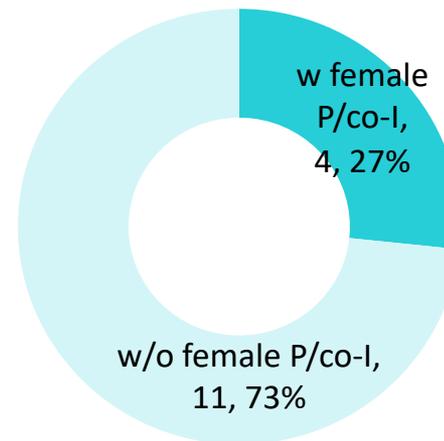
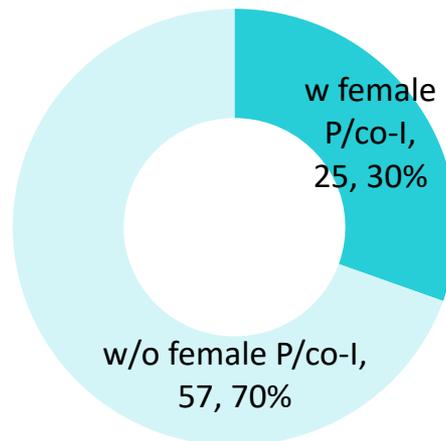
Under-Represented
Minorities



- No bias in review
- Limited pipeline

Room for improvement
→ Work in progress
with C-DOCTOR

Gender



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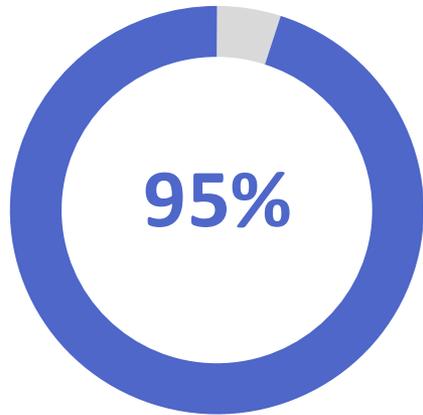
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RESOURCE CENTER IMPACT

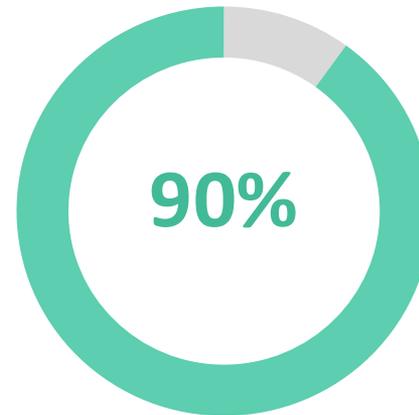
ITP Program in Numbers: Since project start in January 1, 2018



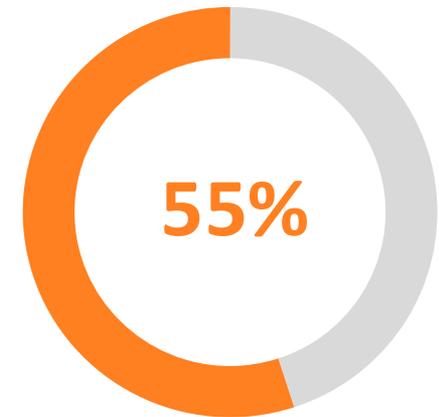
**ITP01-03 teams
with issued/ pending
patent on core
technology**



**ITP01-03 teams
working with the
Market Needs Core**



**ITP01-03 teams
working with the
Regulatory Core/
Institution
Regulatory Support**



**ITP01-03 teams
with submissions to
the FDA**

Projects are well-positioned for Stage 3 Funding and Clinical Adoption



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RESOURCE CENTER IMPACT

ITP Program in Numbers: Since project start in January 1, 2018



20

ITPs Supported



>\$1.9M

**Total funding committed
to ITPs (% DC to Cores)**



> 600 hours

**Market Needs
Core time spent with
ITP teams**



>70%

**% of RC members
serving as ITP
Advisory Team
members**



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UPDATES SINCE JANUARY 2019

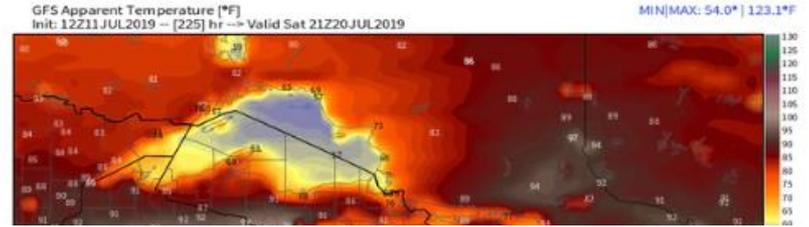
WEATHER

Midwest heat wave to bake 53 million, including Michigan

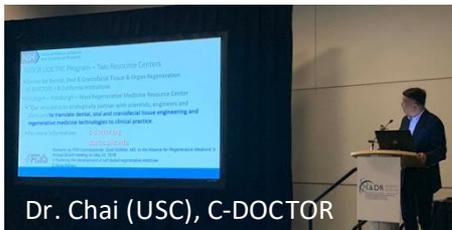
Updated Jul 12, 2019; Posted Jul 11, 2019



Here's a look at the forecast when humidity is factored in and heat index is figured.



IADR/AADR/CADR General Session & Exhibition Vancouver, BC, Canada - June 19-22, 2019

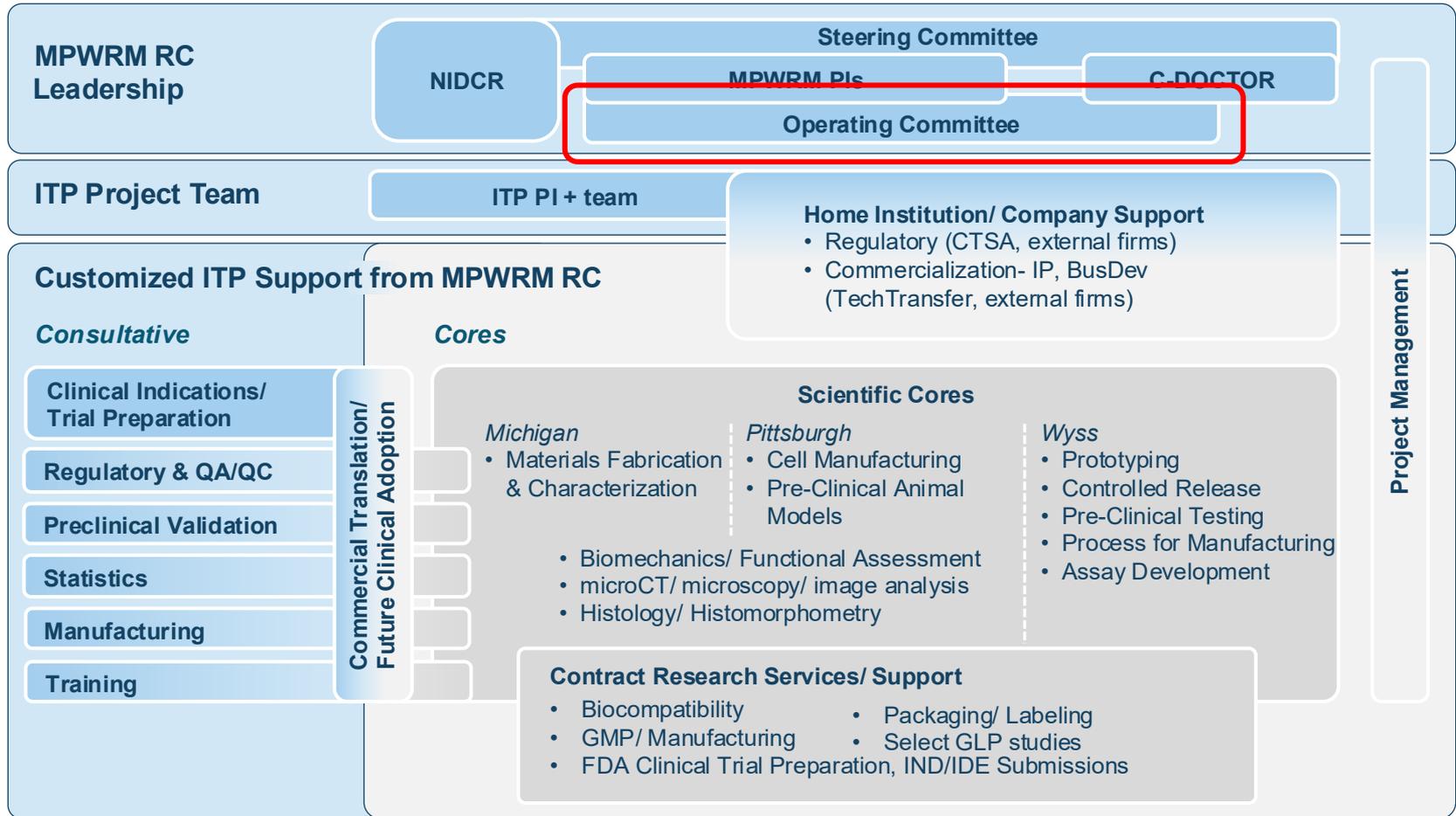


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STAGE 3 SUBMISSION (June 2019)

Revised Resource Center structure to more effectively support ITPs



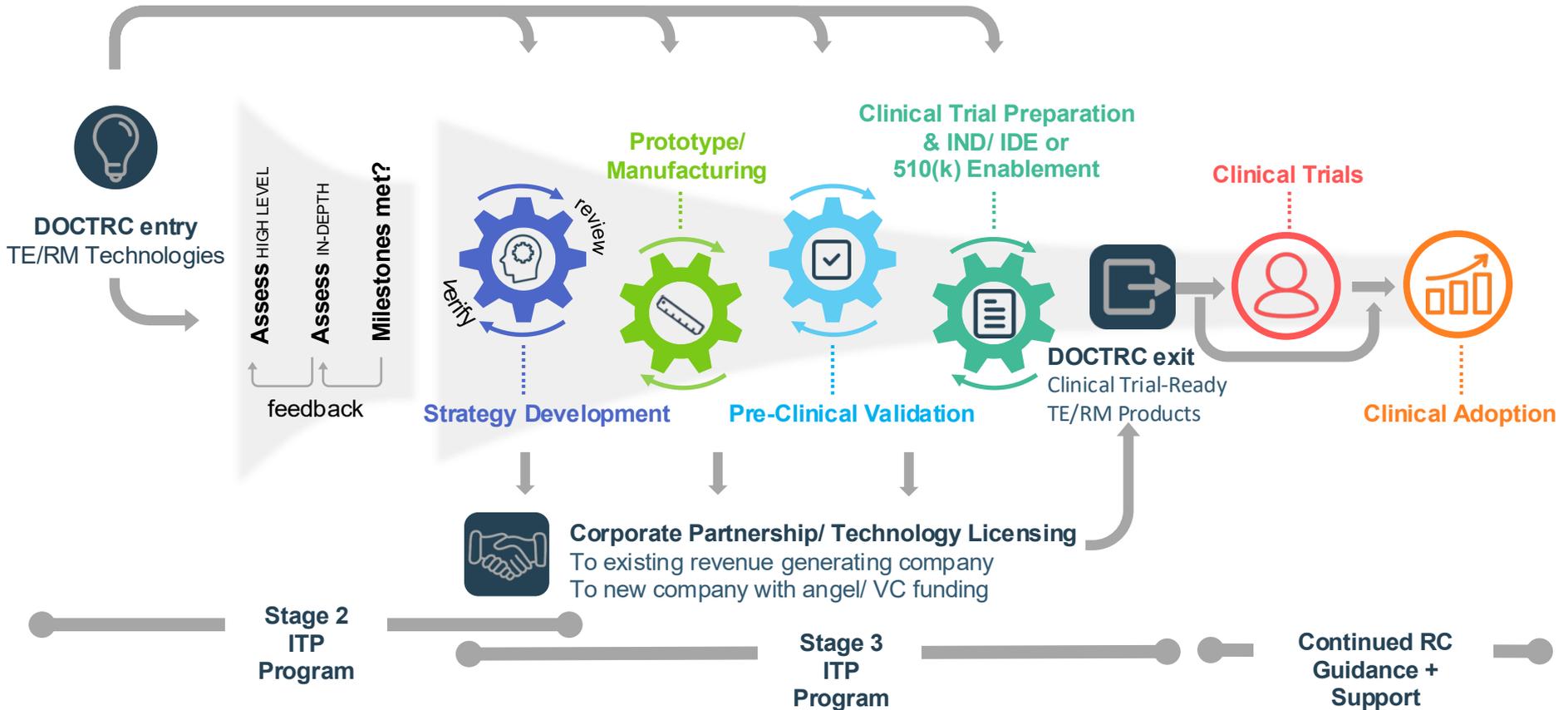
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STAGE 3 SUBMISSION (June 2019)

Revised Resource Center structure to more effectively support ITPs



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STAGE 3 SUBMISSION (June 2019)

Synergistic Collaborations with C-DOCTOR to benefit the larger RM Community



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www.doctrc.com



www.c-doctor.org

Specific Aim #3: Collaborate with C-DOCTOR to benefit DOCTRC as a single Consortium.

Leverage complementarity and benefit the larger RM community/ increase the probability of clinical implementation for our collective ITPs:

- a) Integrate the infrastructure of the two Resource Centers to support ITPs
- b) Share core service support and standardize the path to commercialization and de-risking of ITPs
- c) Cross-validate ITP results across Resource Centers
- d) Provide cross- Resource Centers training opportunities, creating a pipeline



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STAGE 3 SUBMISSION (June 2019)

Leveraged Support from Various Stakeholders

Source

University of Michigan School of Dentistry

University of Michigan Office of the Provost

University of Pittsburgh Senior Vice Chancellor for the Health Sciences

University of Pittsburgh School of Dental Medicine

The Avenues Company | Medical Device Regulatory Solutions, LLC

American Preclinical Services

ITP Project Teams:

Grant submissions- DoD, NIH: UH3/UG3, SBIR

Corporate partners

Home institution support

Outside investment capital

~\$4.5M

in leveraged funding support



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MPWRM RC ACTIVITIES

Looking Ahead...

Continued support for ITPs

- Clinical trial preparation & IND/ IDE or 510(k) enablement
- Market adoption

Adapt programs and Resource Center based on lessons learned

Gear up for Stage 3 of DOCTRC Program

- Implementation of rigorous design controls
- Regulatory training opportunities
- Iteration of commercialization roadmap
- Identification of leveraged funding



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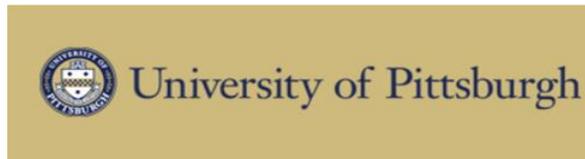
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A BIG THANKS TO...

CORPORATE SPONSORS, MPWRM RC MEMBERS & PARTNERS



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Stay tuned!



www.doctrc.com



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