資料2-3　配布用
第３回橋渡し研究戦略的推進プログラム
中間評価委員会　令和元年６月19日

スタンフォード大学における医学系
Translational Research
&
Entrepreneurship Education

文部科学省　橋渡し研究戦略的推進プログラム中間評価委員会
June 19, 2019

Fumiaki Ikeno, M.D.

- Program Director (U.S) Japan Biodesign, Stanford biodesign Program, Stanford University
- Regional co-director for Asian Pacific, Oceania, SPARK Translational Research Program, SPARK GLOBAL
- Director of Japan reach, Stanford Center for Asian Health Research and Education (CARE), Stanford School of Medicine
- Researcher, Division of Cardiology, Stanford University

Commercialization

Pharma & Bio

Device

スタンフォード大学における医学系 Translational Research & Entrepreneurship Education

1. **Entrepreneurship Education**
   a. Medical Device: Biodesign Program
   b. Drug & Pharma: SPARK Program
2. **Office of Technology Licensing**
3. **Translational Research**
   a. SPECTRUM
4. **Clinical Research**
5. **Out of campus:**
   a. Acceleration Program: Start-X MED
   b. Incubation Company: Fogarty Institute, MBC biolabs, etc

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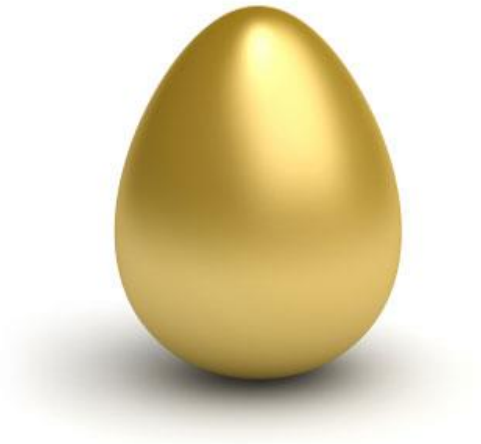
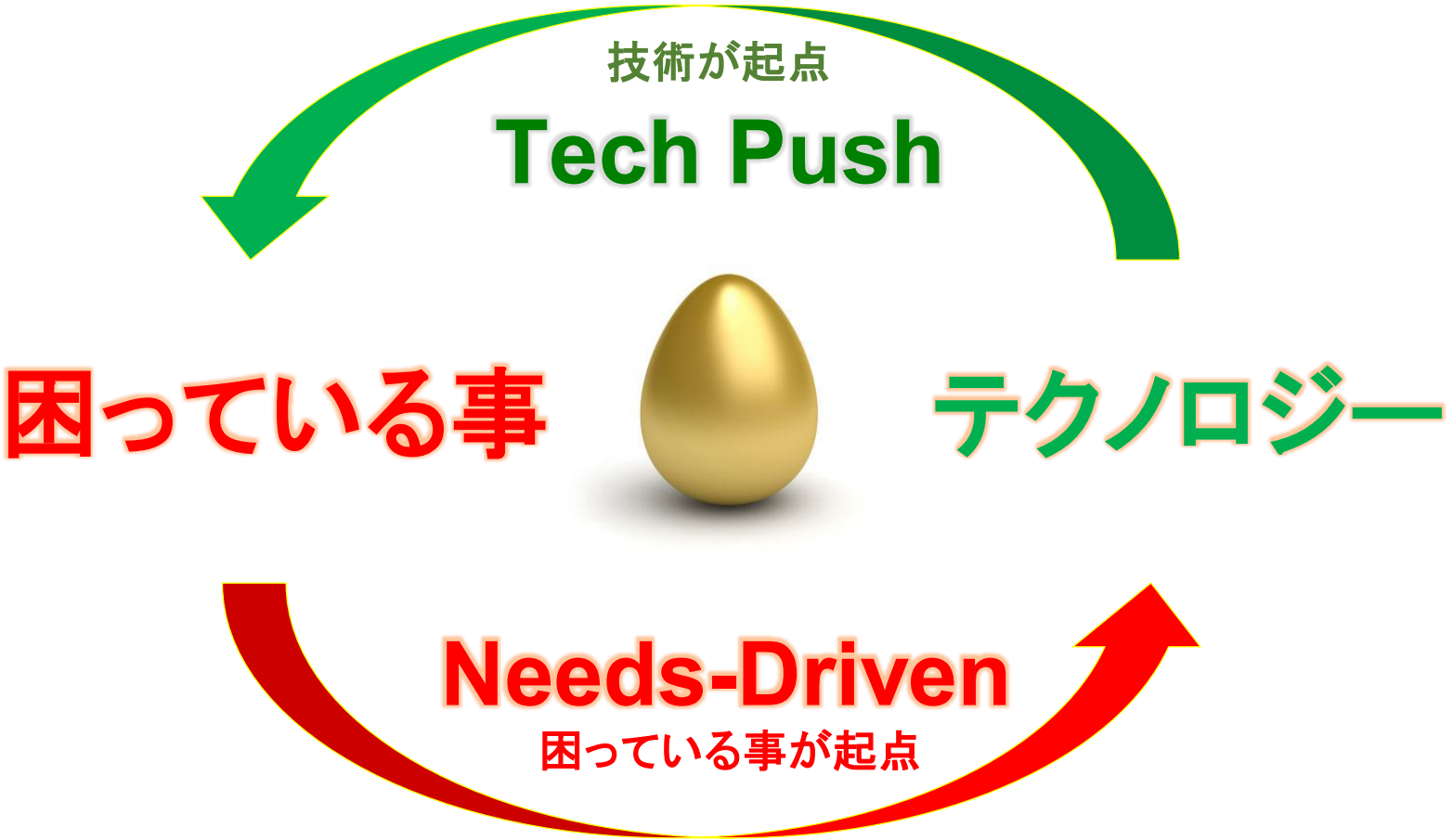


イノベーション

技術が起点

Tech Push



HealthCare Innovation

	Medtech	Biopharma
Disciplines	mech eng elect eng med/surg	chem eng comput sci biology genetics
Innovation Process	needs-driven	discovery plus need

イノベーション

技術が起点

Tech Push

困っている事

テクノロジー

Needs-Driven

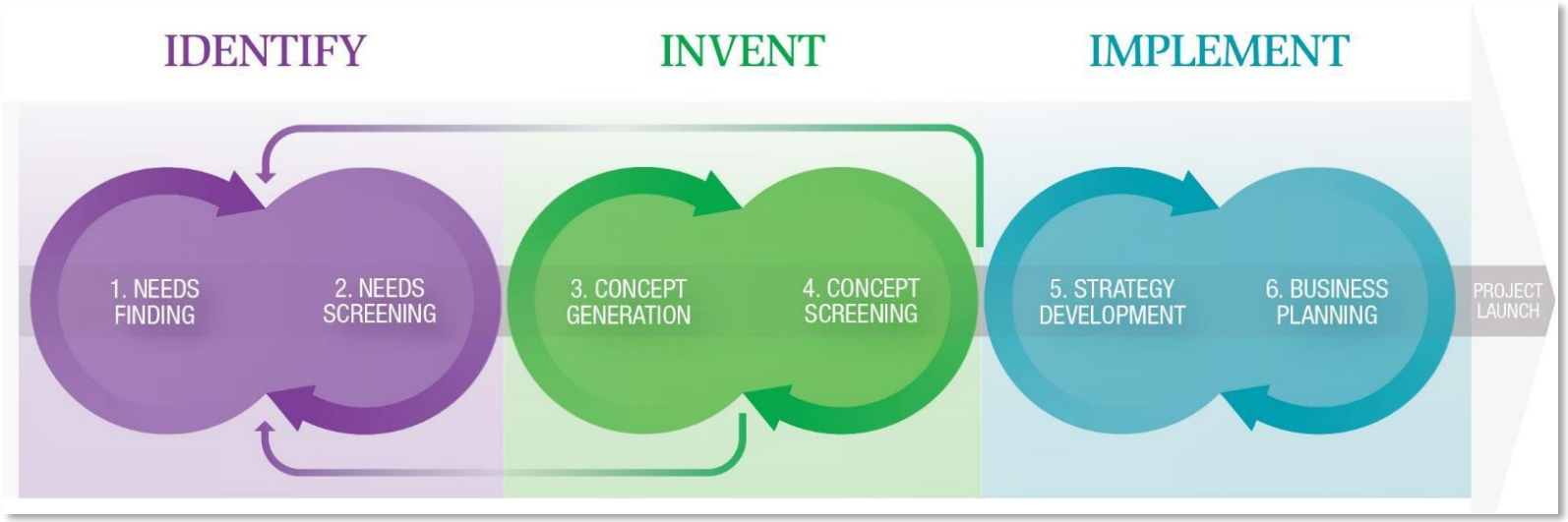
困っている事が起点

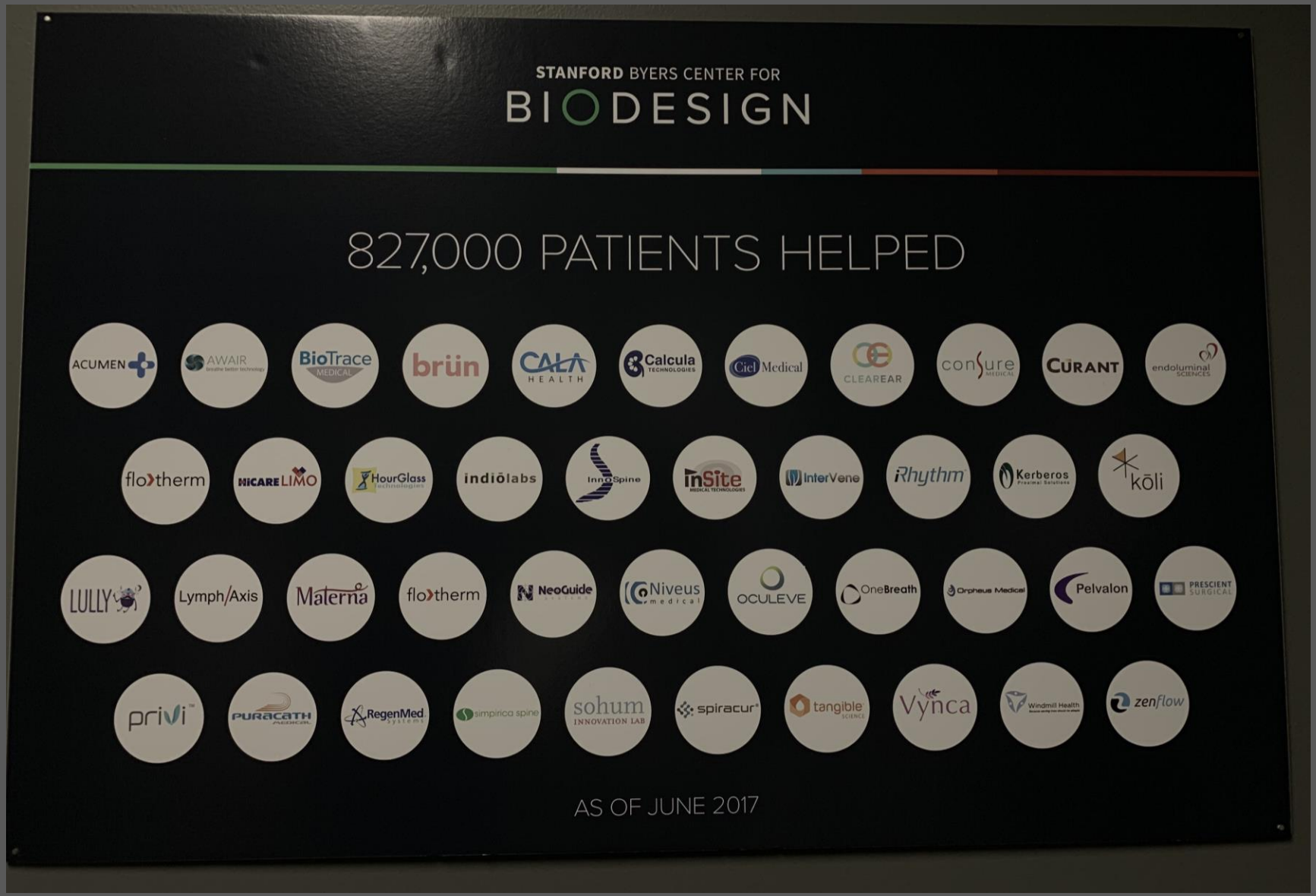
STANFORD BYERS CENTER FOR BIODESIGN

Since 2001

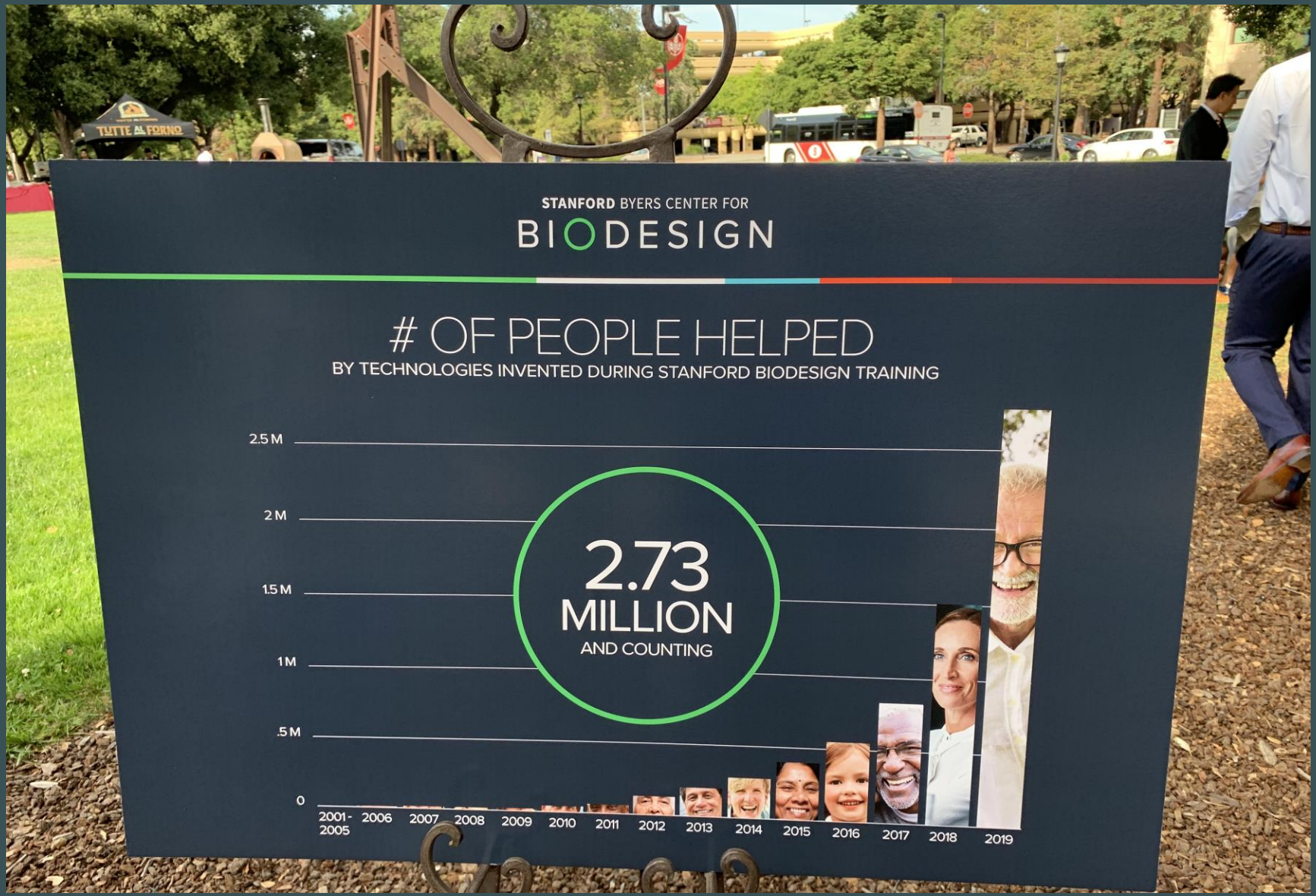
Stanford Byers Center for Biodesign
218 Campus Drive
Stanford, CA 94305

Steps in the Biodesign Process




STANFORD BYERS CENTER FOR
BIODESIGN
827,000 PATIENTS HELPED
ACUMEN
AWAIR
BioTrace MEDICAL
brün
CALA HEALTH
Calcula TECHNOLOGIES
Ciel Medical
CLEAREAR
consure MEDICAL
CURANT
endoluminal SCIENCES
flowtherm
HICARE LIMO
HourGlass technologies
indiolabs
InnoSpine
InSite MEDICAL TECHNOLOGIES
InterVene
Rhythm
Kerberos Proximal Solutions
kōli
LULLY
Lymph/Axis
Materna
flowtherm
NeoGuide
Niveus medical
OCULEVE
OneBreath
Orpheus Medical
Pelvalon
PRESCIENT SURGICAL
privi
PURACATH MEDICAL
RegenMed Systems
simpirica spine
sohum INNOVATION LAB
spiracur
tangible SCIENCE
Vynca
Windmill Health
zenflow
AS OF JUNE 2017


STANFORD BYERS CENTER FOR
BIODESIGN
INNOVATION FELLOWSHIP ALUMNI CAREER PATHS
CLINICAL/
ACADEMIC
INNOVATORS
CORPORATE/
ENTREPRENEURIAL
INNOVATORS


TUTTE AL FORNO
STANFORD BYERS CENTER FOR
BIODESIGN
OF PEOPLE HELPED
BY TECHNOLOGIES INVENTED DURING STANFORD BIODESIGN TRAINING
2.5 M
2 M
1.5 M
1 M
.5 M
0
2.73
MILLION
AND COUNTING
2001 - 2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019

イノベーション

技術が起点

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困っている事

テクノロジー

Needs-Driven

困っている事が起点

SPARK

AT STANFORD

How academic research can contribute to patients' care

Since 2006

SPARKmed.Stanford.edu

SPARK Advisors – Our Key Component for Success

SPARK outcome: *51%* success of 106 graduating projects

48 **projects licensed**:

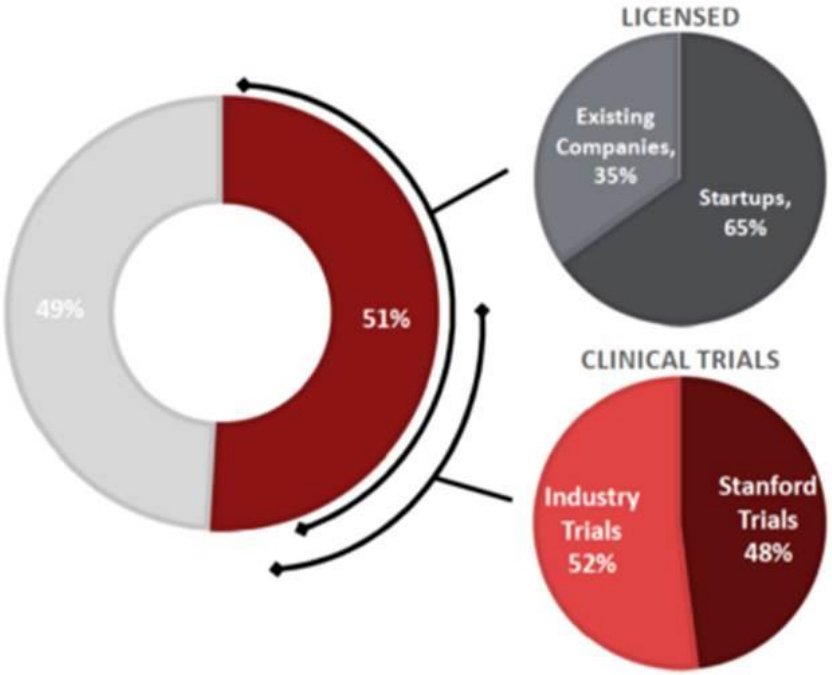
30 start ups

16 existing companies

25 **clinical trials:**

12 trials at Stanford

13 trials in industry



CHRI **SPARK** Graduates = *58%* success

CHILD HEALTH RESEARCH INSTITUTE

10 **projects licensed**:

- **6** start ups
- **4** existing companies

4 **clinical trials:**

- **1** trials at Stanford
- **3** trials in industry

26 **projects are on going:**

- **9** Rare diseases
- **6** Cell Rx, genome editing, gene Rx
- **2** Psychiatric
- **5** Anti-viral, bacterial and vaccine
- **3** Anesthesia and post-op

Some of the startups of the **SPARK** projects and their pharma partners

12

SPARK AT STANFORD

SPARK Taiwan [2/2]

- Number of projects:
  - Start: 20 projects (from National Taiwan University & National Cheng Kung University)
  - Currently: Upgraded to 228 projects in Jun -18
  - Future: Average 10~20 projects in 6 AUs (depends on funding)
- Faculty and mentors (SPARK Taiwan and AUs):
  - Director: Dr. Y. Jane Tseng
  - Execution Units:
    - STPI, NARLabs
  - Mentor pool: > 90 mentors
    (business, finance, R&D, research, clinical, IP, regulatory, etc.)
- Spectrum of projects:

25% Medical Device
20% Drug development
21% Diagnostics
12% Biomaterials

10% Bioinformatics
12% Rehabilitation, cell therapy, vaccine, healthcare, biomarker...

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STANFORD UNIVERSITY
OTL
OFFICE OF
TECHNOLOGY
LICENSING

New Disclosures

- In FY2017, we received 477 new technology disclosures.
- One of the most challenging responsibilities for OTL is to decide whether or not to spend University funds on filing patents.

Royalty

- In FY2017, Stanford received $45.4M in gross royalty revenue from 808 technologies, with royalties ranging from $1.26 to $11.1M.
- 56 of the 808 inventions generated $100,000 or more in royalties.
- 5 inventions received $1M or more.
- We have a long tail of inventions that bring in less than $100,000 in royalties, but this long tail creates a steady royalty base for Stanford.

Licensing

- OTL evaluated 477 new invention disclosures and signed 157 new licenses.
- 80 of the licenses were nonexclusive, 36 were exclusive and 41 were option agreements.
- 22 of the 157 agreements were with Stanford start-ups and 19 of them involved equity.

Royalty Distribution

- Stanford's royalty-sharing policy provides for the distribution of cash net royalties (gross royalties **less 15% for OTL's administrative expenses, minus direct expenses**) to inventors, their departments and their schools.
- OTL distributed personal income totaling $10.40M to **736** inventors.
- Stanford departments received $9.06M and schools received $8.66M after the University assessed an infrastructure charge on their shares of royalty income.

Expense

- Filing and maintaining patents is an expensive proposition and we spent $10.9M in legal expenses with more than 50% of legal expenses eventually reimbursed by licensees or royalty payments.
- Our operating budget for the year (excluding patent expenses) was $8.1M.

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Stanford MEDICINE | Spectrum

The Stanford Center for Clinical and Translational Research and Education

Spectrum

The Stanford Center for Clinical and Translational Research and Education

Resources for Researchers

!

The Freidenrich Center for Translational Research is a state-of-the-art facility for designing and conducting human-subject clinical trials, available for use by all Stanford researchers.

CLINICAL RESEARCH SUPPORT

Our staff can help you with all stages of human research and clinical trials including:

- Study design
- Biostatistics
- Budgets & contracts
- Patient enrollment
- Regulatory approval
- Final reporting & publishing

New onlline tools that save researchers time

Visit the Spectrum website for a roadmap and the Study Navigator collaboration tool to help you manage your clinical trial.

To schedule time with a study facilitator at Spectrum's Office of Training & Compliance (OTC):
studyfacilitator@stanford.edu

Or go to the Spectrum website here:
http://spectrum.stanford.edu/

EDUCATION & MENTORING

Spectrum runs short- and long-term education and mentoring programs, helping to advance the careers of clinical & translational researchers. Our Intensive Course in Clinical Research (ICCR) helps clinical fellows and junior faculty learn how to set up a clinical trial in just five days.

Spectrum education offerings

KL2 Mentored Career Dev't Award
TL1 Pre- & Postdoctoral Research Training Award
Intensive Course in Clinical Research (ICCR)
Good Clinical Practice (GCP)
Biostatistics 101
How to prepare for an FDA audit
Navigating research at Stanford and more...

To learn more about training, visit:
http://spectrum.stanford.edu/training-mentoring.html

INNOVATIONS & PILOTS

The Biodesign, SPARK and Diagnostics programs accelerate device, drug and diagnostics discovery through pilot grants; lab access; mentors; training; and assistance on regulatory approvals and intellectual property law.

Programs to help innovators move their ideas from benchtop to bedside

Many innovations, such as this low-cost newborn warmer, are designed to address the needs of global or underserved populations

For more information on Biodesign:
http://biodesign.stanford.edu/
biodesign@stanford.edu
(650) 736-1158

For more information on SPARK or Diagnostics programs:
http://sparkmed.stanford.edu/
sparkmed@stanford.edu
((650) 721-6185

CORE RESOURCES

Spectrum provides centralized management of technology core services such as pre-clinical animal translational testing, human immune monitoring, genetic analysis, and high-throughput chemical, siRNA, cDNA, and content screens.

Core resources

Bioinformatics Resource Center
Cognitive NeuroScience Facility
Data Coordinating Center (DCC)
Surgery FACScan Center
High-Throughput Bioscience Center
Human Immune Monitoring Center
Magnetic Resonance Spectroscopy
Stanford Behavioral & Functional Neuroscience Laboratory
Tissue Bank
Clinical Informatics

To learn more about core resources available to clinical researchers visit:
http://spectrum.stanford.edu/

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Stanford
Cancer Institute
A National Cancer Institute
Comprehensive Cancer Center
Stanford MEDICINE


Stanford
MEDICINE
Cardiovascular
Institute


Lucile Packard
Children's Hospital
Stanford


Stanford
MEDICINE

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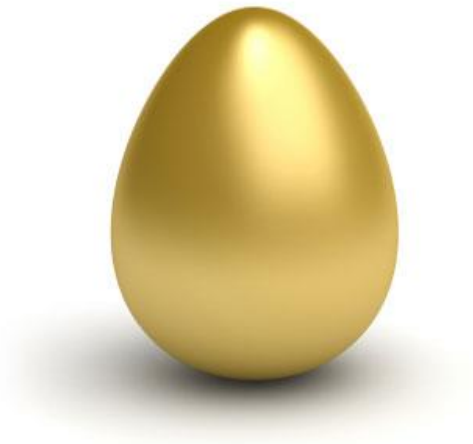
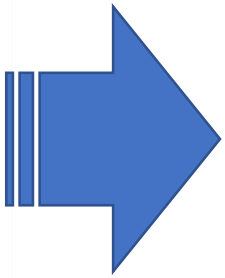
Acceleration Program

StartXMed

起業後は？



起業



インキュベーションカンパニー

Fogarty Institute
for Innovation

biolabs
Enabling awesome

日本国として橋渡し研究をどうしたいか？

・日本の橋渡し研究が目指すべき方向性（世界展開等）
・ＡＲＯ１（非臨床部分）とＡＲＯ２（臨床部分）のバランス
・知財等に関し、外部人材の活用や拠点機能のシェアリングを推進
・プロジェクトマネージャー等の支援者や研究者に対する教育は大切
・支援者のキャリアパス（人材流動、キャリアステップアップ）
・拠点もブランディング化が重要（国による認定制度化？また、拠点による社会へのインパクトを示すことも必要）