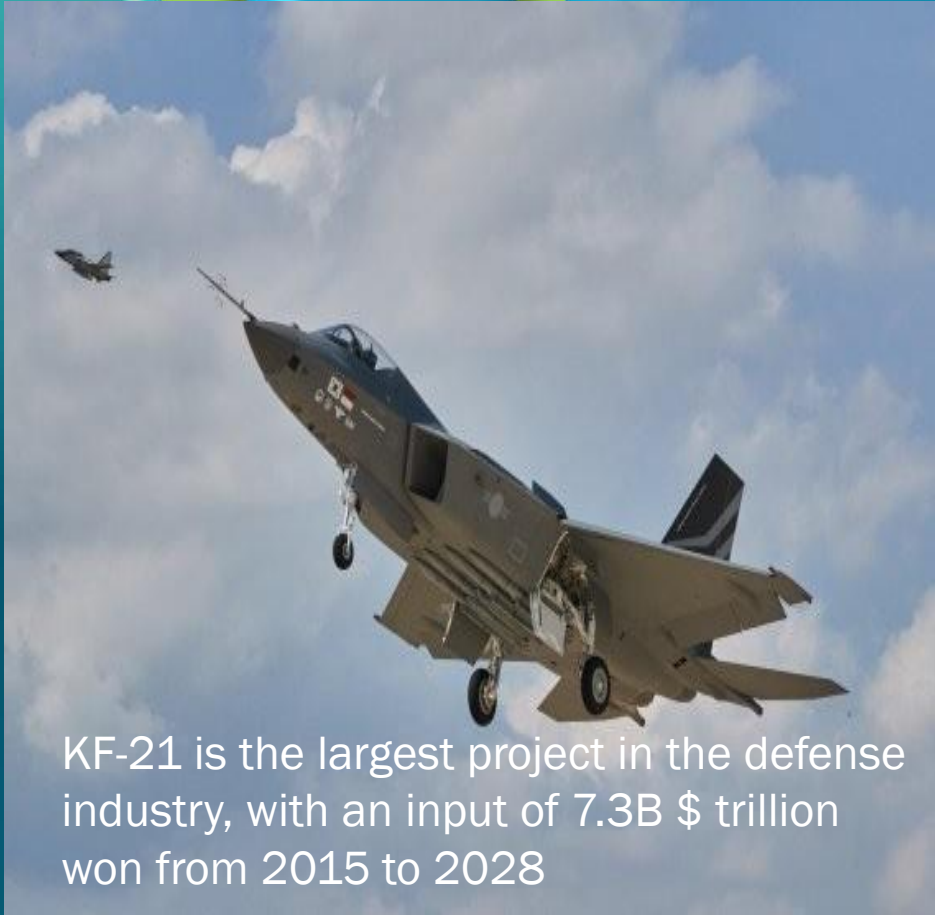


# Change, Challenge Chance “K ARPA-H”

31<sup>st</sup>. Aug, 2022

**Gusun Park, PhD.** Senior Research Fellow  
Korea Research Institute of Standards and Science(KRISS)  
Korea Institute of S&T Evaluation and Planning(KISTEP)



KF-21 is the largest project in the defense industry, with an input of 7.3B \$ trillion won from 2015 to 2028

Source : new.naver.com

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## CHANGE

1. DARPA's approach to R&D and Innovation
2. Competition and Monopoly for Innovation
3. PM or PD' : R&R of Healthcare R&D

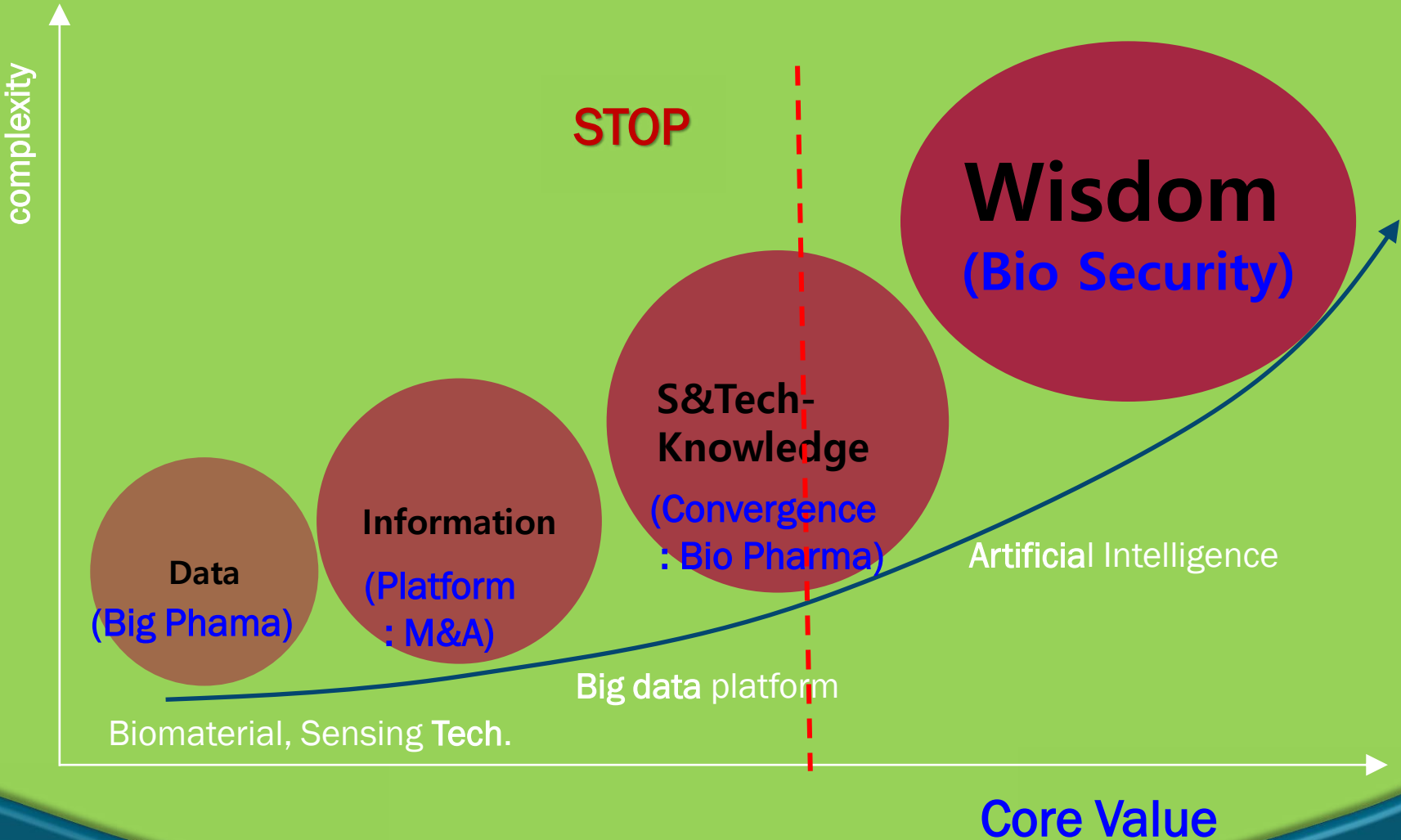
## CHALLENGE

1. Does the perfect competition also make the ecosystem healthy in R&D area?
2. Many failures make a success story
3. The role of regulation should be a safeguard, not an obstacle

## CHANCE

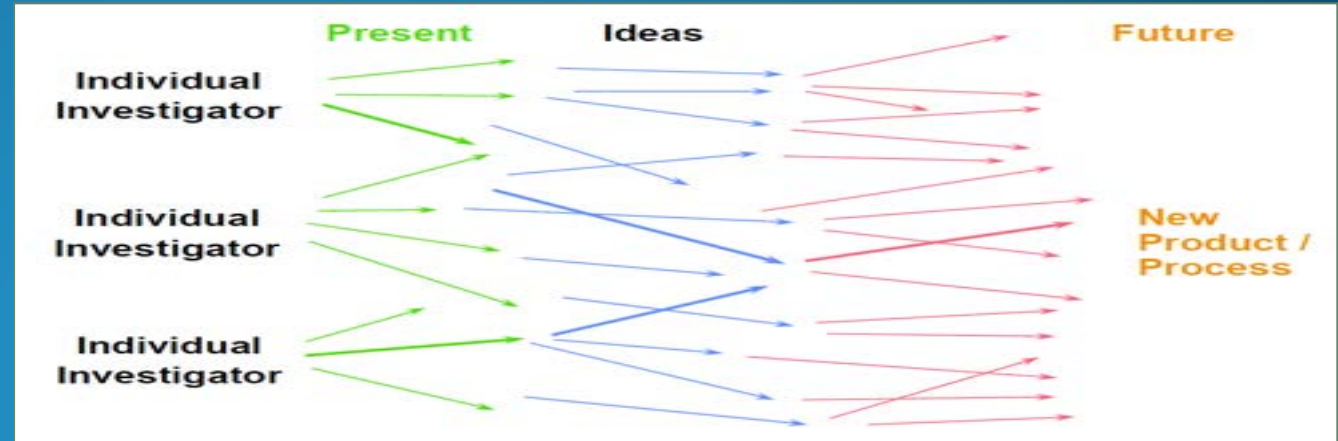
1. 4P - Prediction, Prevention, Personalization, Precision
2. Human Health to One Health
3. K-Power, K-Possibility

# CHANGE



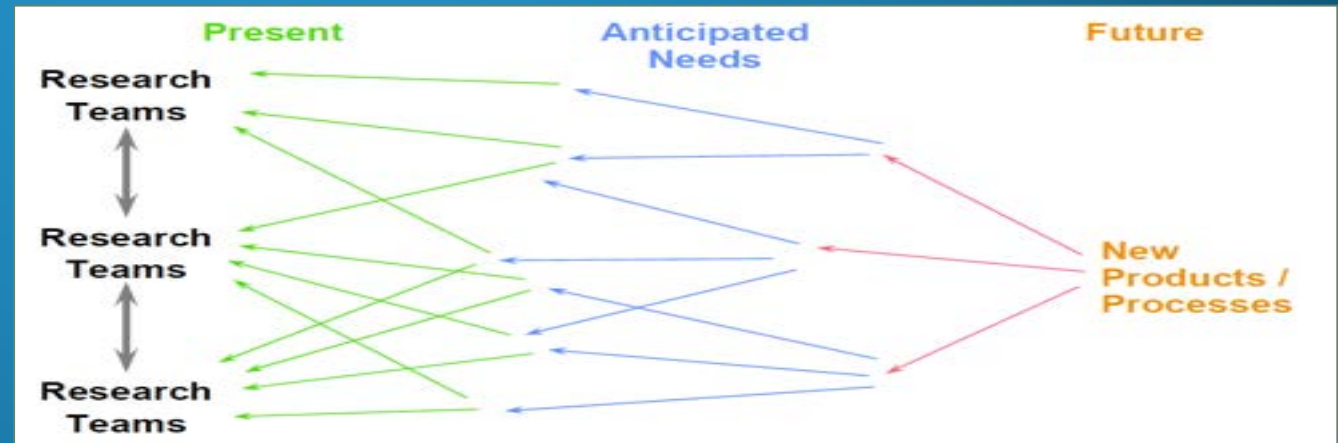
# Change I , DARAPA's approach to R&D and Innovation

Typical Approach



DARPA:

*End-game Approach*





## Change II, Competition and Monopoly for Innovation

For Innovation, “a creation-based monopoly system”,  
not “a competition-based monopoly”, needs to be allowed.



"The Excellence of research is so great that we dare  
not even put forward similar studies.

It starts with choosing a team of researchers with  
R&D and innovation capabilities."

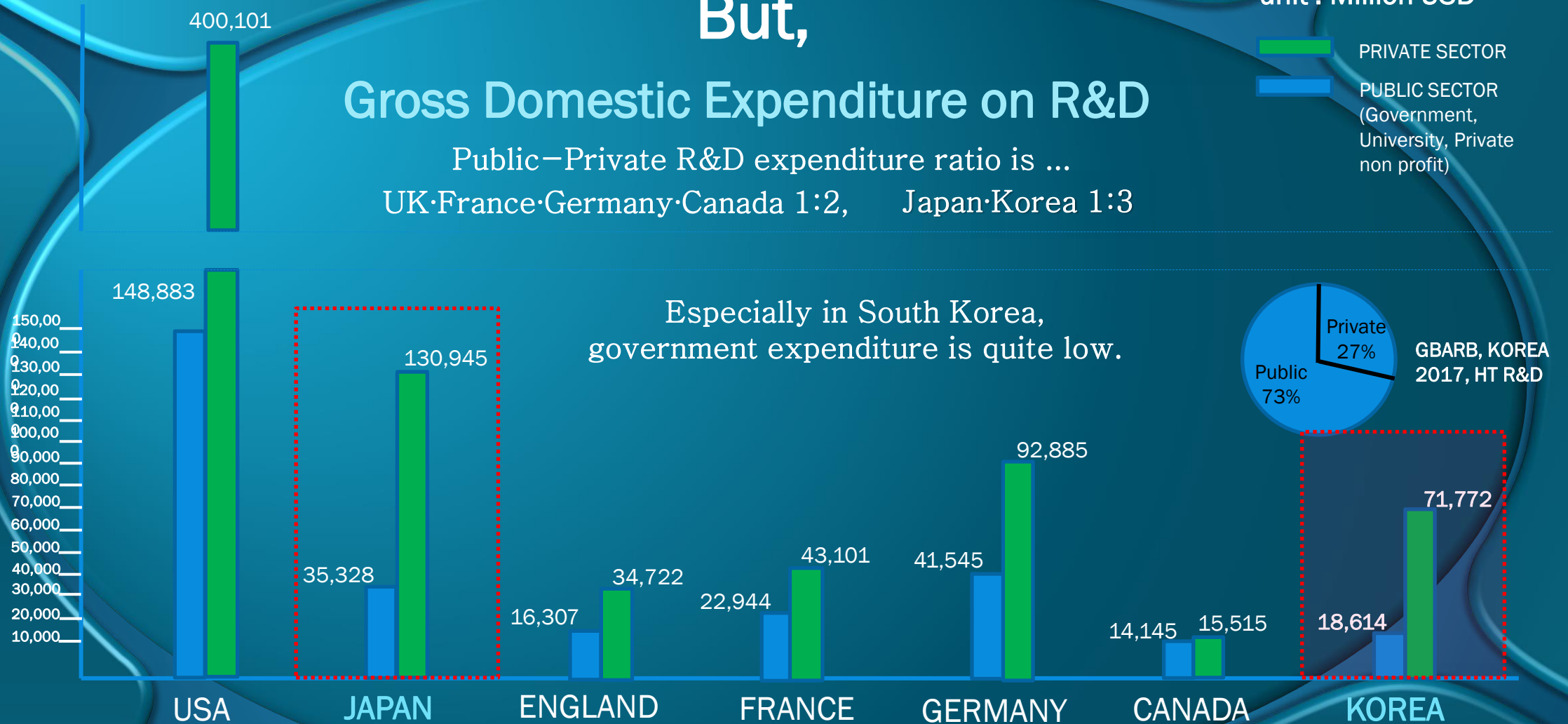
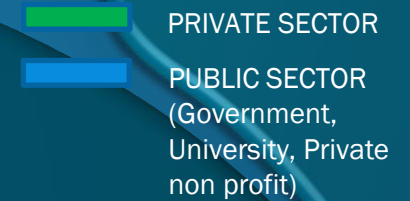
Peter Thiel

# But,

## Gross Domestic Expenditure on R&D

Public-Private R&D expenditure ratio is ...  
UK·France·Germany·Canada 1:2, Japan·Korea 1:3

unit : Million USD



Source : OECD Stat.-Data by theme : Science, Technology and Patents : R&D Statistics : Expenditure : Gross domestic Expenditure On R&D by sector of performance and source of funds(OECD Statistics 2020.04.22), 2017

## Change III, PM or PD' : R&R of Healthcare R&D

The authority for research projects....'Nothing',

But The responsibility to research results...'Everything'

“The role of PM or PD should be a Designer as well as a Manager and a Director”

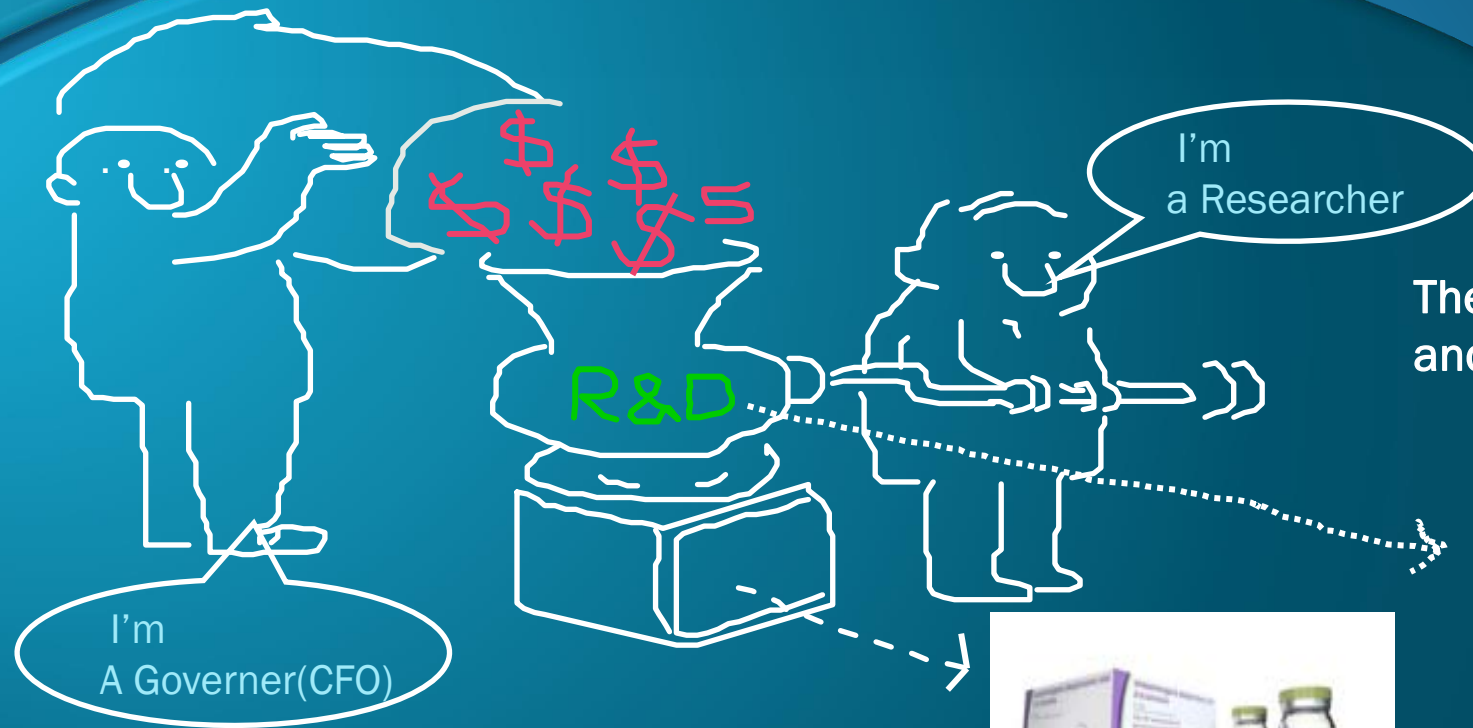
### “Union Model”

“Union Model” is a model that is able to performs all three roles,  
Manager, Director and Designer

PD or PM should manage the project as a manager and a director, moreover  
play a role of designer who is responsible for the value of planning  
and results and the consumer choice



# If Not



There is no original technology and innovation, but only PPP\*

\*Paper, Patent, Proposal



Full of regulations

**“Innovation...”** Peter Thiel

It's easier to copy a model than to make something new. Doing what we already know how to do takes the world from 1 to n, adding more of something familiar.

But every time we create something new, we go from 0 to 1.

The act of creation is singular, as is the moment of creation, and the result is something fresh and strange”



# CHALLENGE

## Global ShutDown



Source : [www.naver.com](http://www.naver.com)

## Economic Impact



## Anomy Chaos

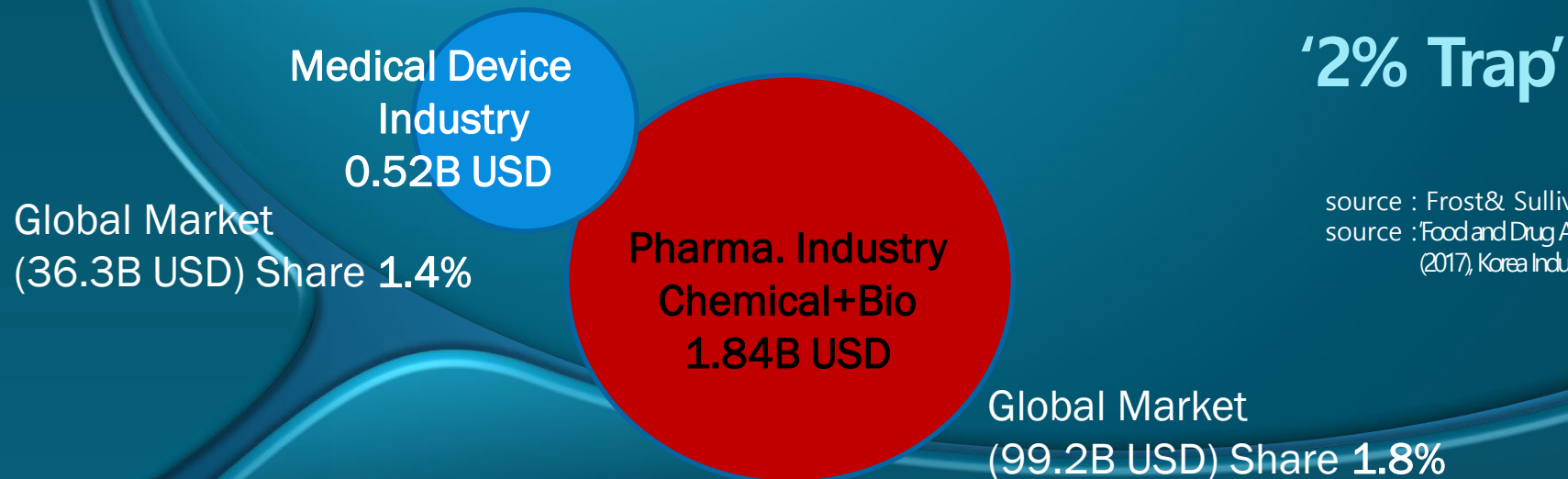


Source of figure : [www.pexels.com](http://www.pexels.com)

# Challenge I , Does the perfect competition also make the ecosystem healthy in R&D area?

Technology Transfer rate(gov. R&D, univs. and gov.-affiliated research ins.) is 2.2%  
(2020 Performance Analysis Report/KISTEP)

- 1) Mismatch between supply and demand (KISTEP, 2022)
- 2) Only 9.5% of institutions have experience using excellent performances (KISTEP, 2022)
- 3) Knowledge transfer between industry and academy is ranked 30th (IMD, 2022)

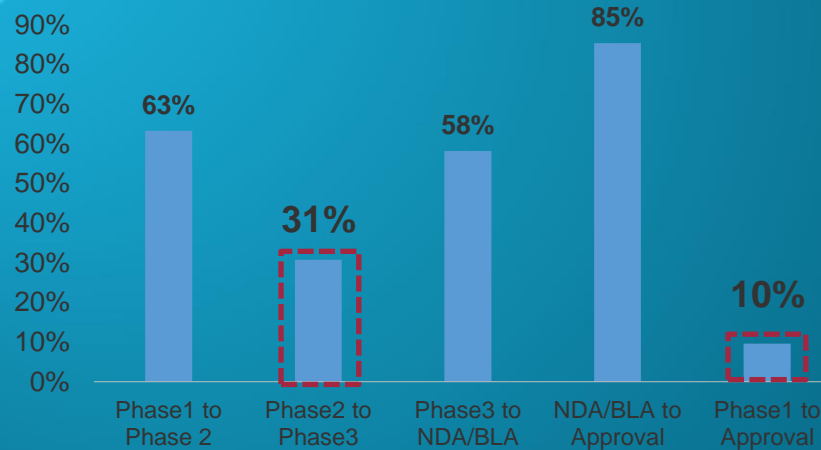


source : Frost& Sullivan, Global Healthcare Industry Outlook 2018  
source : Food and Drug Administration Press Release by Korea Drug Import and Export Association (2017), Korea Industry 2030(2019)



# Dilemma of Biohealth Industrialization

### Success Rate of FDA Approved Clinical Tests

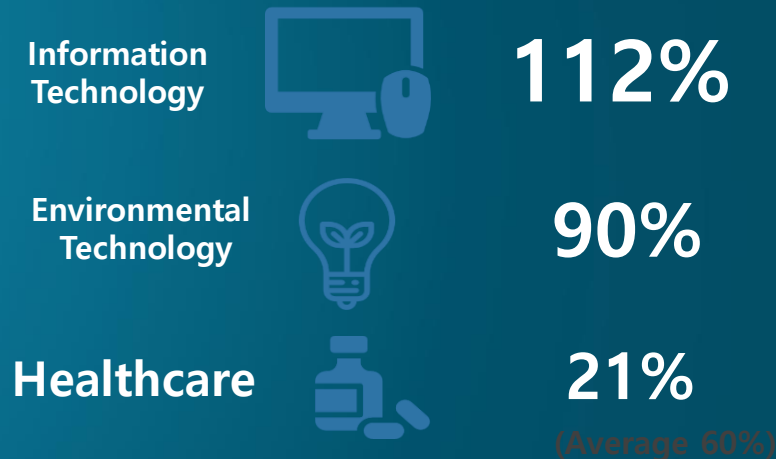


(Sources: FDA, Amplion, Biomedtracker, Biotechnology Innovation Organization)

NDA - New Drug Application,  
BLA - Biologic License Application

- The success rate for Phase 2 is usually very low because it is first phase for testing possible side effects to the body
- Globally, about 1~2 billion dollars are spent for a new drug development and in average **takes about 10 years** to finish
- From 2006 to 2015, the overall success rate of new drug developments passing all the phases and getting approved by FDA is **approximately 9.6%**

### Ratio of Commercialization Relative to Number of Published Papers



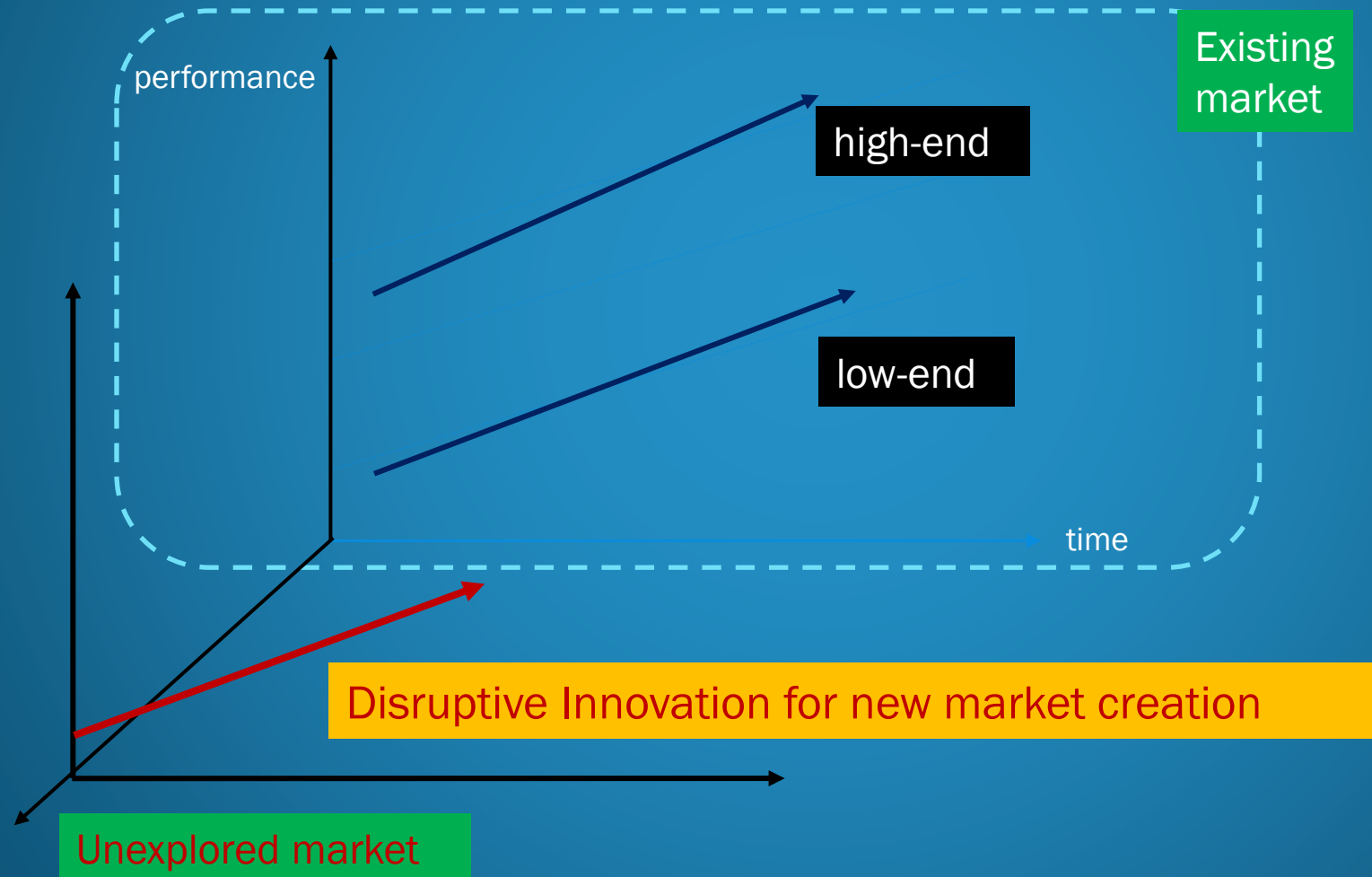
Source: <http://www.sentv.co.kr/news/viewn/681454>

- Although the number of published papers under government funded programs for bio and healthcare is overwhelming number one over other categories, commercialization rate for bio and **healthcare ends at 21%**
- In order for more effective commercialization, there is a need for a control tower encompassing companies, hospitals and start-ups.

This particular inefficiency at applying and commercializing research findings is characteristic of biohealth industry and more commonly referred to as **the Valley of Death**



# First Mover vs. Last Mover



-True & Lie -

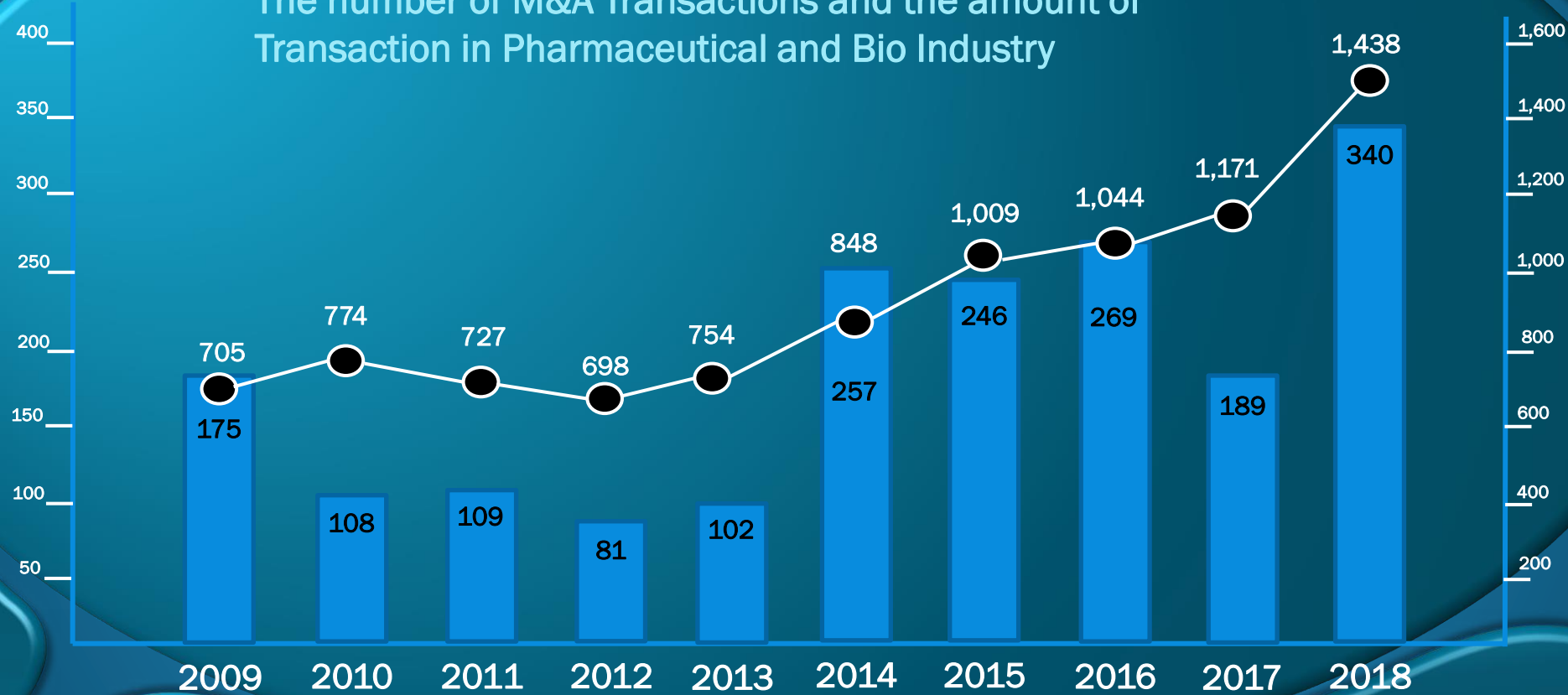
It is better go late than  
not to take the 1<sup>st</sup> place?

# First Mover Advantage

(Transactions)  
unit : Billion \$

(Transaction Amount)  
unit : number of case

The number of M&A Transactions and the amount of Transaction in Pharmaceutical and Bio Industry



Source : Bloomberg, Samjung KPMG Economy Institute

Note : As of the date of publication of 2018.12.31, including proposals, progress and completion transactions. (Except for destruction transactions)

# Challenge II, Many failures make a success story

## Value of Innovation in Korea, Ask K-BioHealth



(Market capitalization 45B \$,  
Sales 5.8B \$)



(Market capitalization 32.5B \$,  
Sales 9.1B \$)



(Market capitalization 17.5B \$,  
Sales 88B \$)



(Market capitalization 14.2B \$,  
Sales 14.8B \$)

(Samsung Electronics : Market capitalization 260B \$, Sales 192B \$)



# R&D vs “Experimental & D(E&D)”

Empirical Development, similar with research activities, is an creative and systematic activity that can achieve another important knowledge and information, which should be combined with the production and improvement of new products or processes based on the knowledge from researches and experiences.

# R&Expreimentation Tax Credit Expansion and perpetuation (Obama Administration, 2015) #

K-ARPA should be a high risk researches and a challenging game changer research that deals with social problems for the future based on innovation, not a means to secure a budget by using a good name.



Source : STEPI by Congressional Research Service(CRS, 2018) and Office of management & Budget(OMB, 2020)

# Challenge III, The role of regulation should be a safeguard, not an obstacle



Ministry of Food and Drug Safety : Your Industrialization is Our Standard

Research  
Achievement

Commercialization

Merchandization  
and  
Industrialization

10,000 Candidates > 10 Pre-Clinical Trials > 3 Clinical Trials > 1 Licensed for Sale > Market Survival

- **Success possibility : 0.0001%, Average period : 15 years, Average cost : 2.3B \$** -

Source : Ministry of Science, Technology, Information and Communication, Bioeconomic Innovation Strategy 2025

Source : MaeKyung News, 'From the needle hole to the birth of the New Testament... Eco of New Drug Clinicians', 2017

# CHANCE

RAPID CHANGE ERA : Dream Big and Think Different



Jeanne d'Arc Syndrom

(1,337year)Crossbow and Knight vs (1,429year) Cannon

Regional Disputes vs Holy war

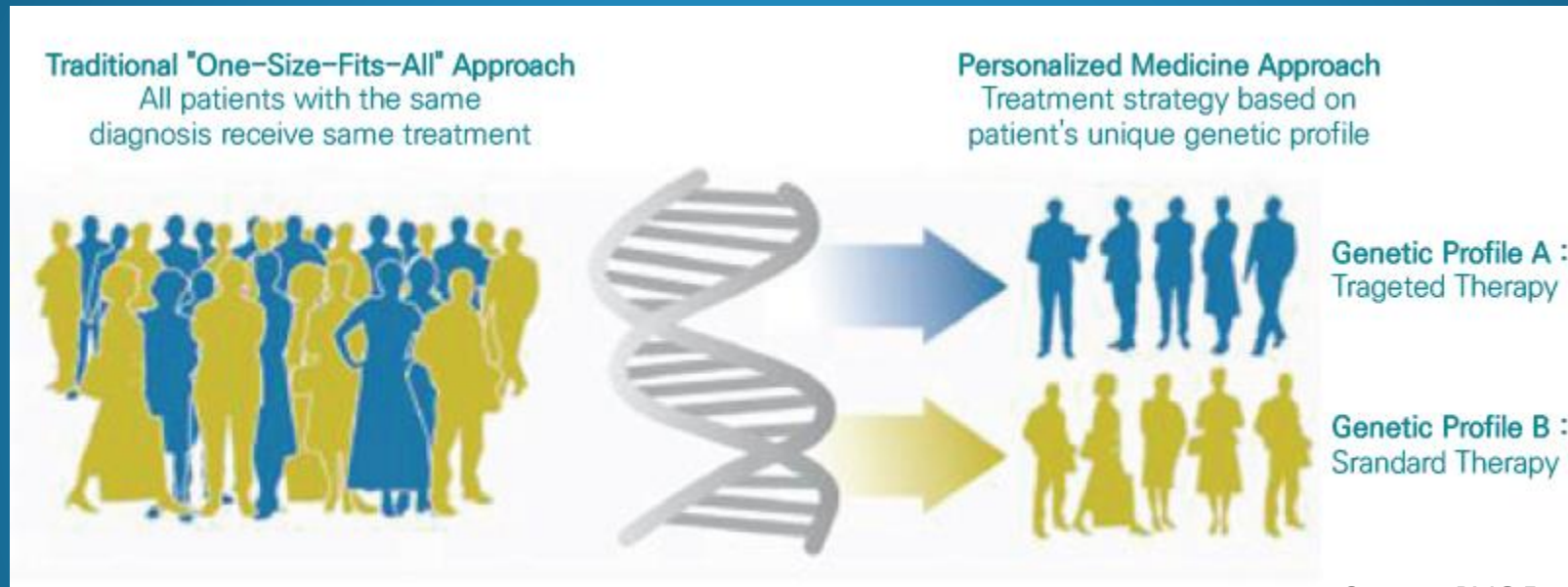
Heavy-armed Assault tactics vs Mounted tactics

**We need to break out the stereotypes from  
the traditional industrial system**

Source : <https://upload.wikimedia.org/wikipedia/commons>



# Chance I , 4P Prediction, Prevention, Personalized, Precision



Sources: PMC Fact Sheet

Predictive & Preventive : Creating New Medical Industries

Precision & Personalized : Clinic Better

➔ Change in New Drug & Medical Device Ind., Challenge and Chance

# Chance II, Human Health to One Health

**DX**Digital Transformation - **EX**Energy Transformation

**BX**Bio Transformation



Source : [www.uarctic.org](http://www.uarctic.org)

**BC to AD**  
**Industrial**  
**Reconversion**

# Chance III, K-Power, K-possibility



K-POP, BTS

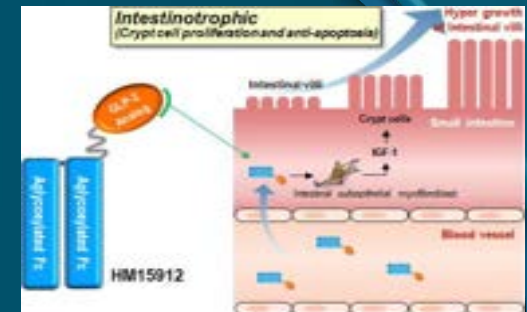
Source : [www.naver.com](http://www.naver.com)



K-MOVIE, BJH



K-SOCCER, SHM



K-BIO, HANMI(?)



Source : [www.BBC.com](http://www.BBC.com)

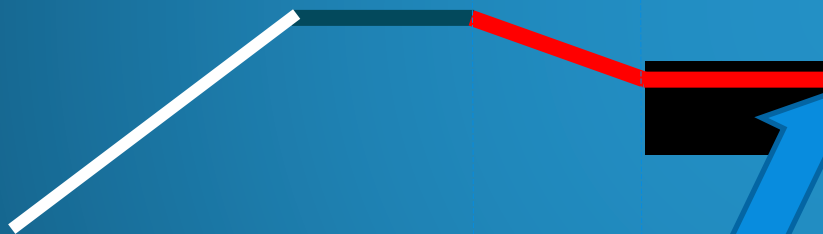
Licensing criteria required for the world's first development: Cases in developed countries(?)



# Game Changer : BIO

Growth

(BC) Before Corona : New Normal



New Deal and Economy

(AD) After Disease : Super Normal



Source : Bio USA, 2018

Time

# Thank you for Listen



Source : [www.pexels.com](http://www.pexels.com)

**If it's the way we have to go,  
we have to start first**

“K-Bio Vaccine Fund 0.41B \$ → 0.82B \$”

“For New drugs Pipeline, 1.8B \$ R&D support by 2030”

“Policy supports(Authorization, Finance, Tax, government Funds etc)”

→ “Investment in private sector 10B \$”

Source : Bio-Industry vitalization strategy(2022.07, MOHW)