

2025 테크 퀘스트

국산 BCI 상용화 성공 사례 및 향후 전망

의료 환경, 규제 및 국제표준을 중심으로

Kiwon Lee, PhD

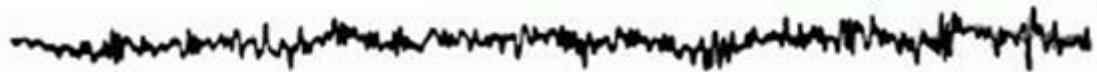


2024. 10

Brain Activity – Emotion / Depression



Special!



Meaningless...



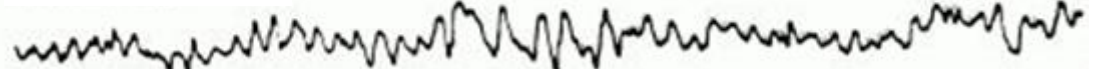
Brain Activity – Cognition, Aging / Dementia



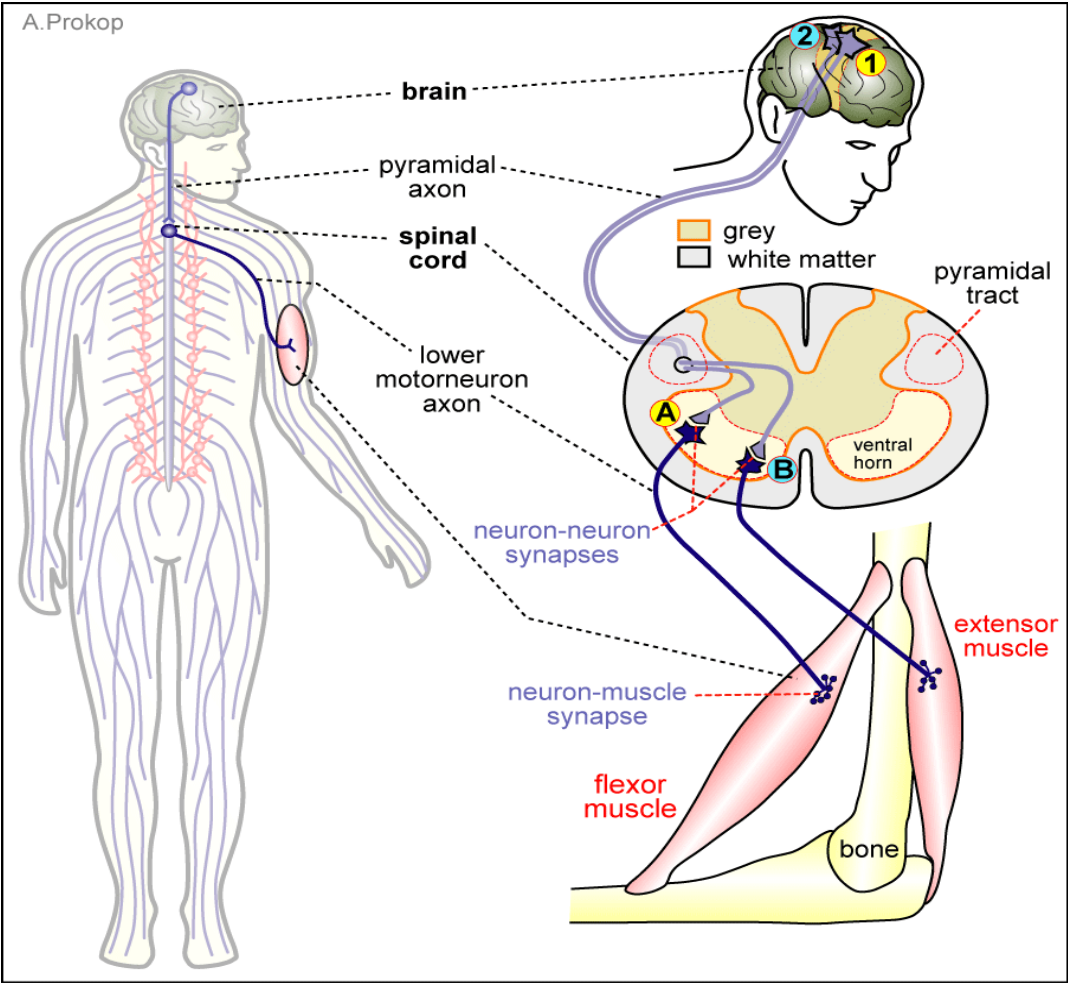
Young



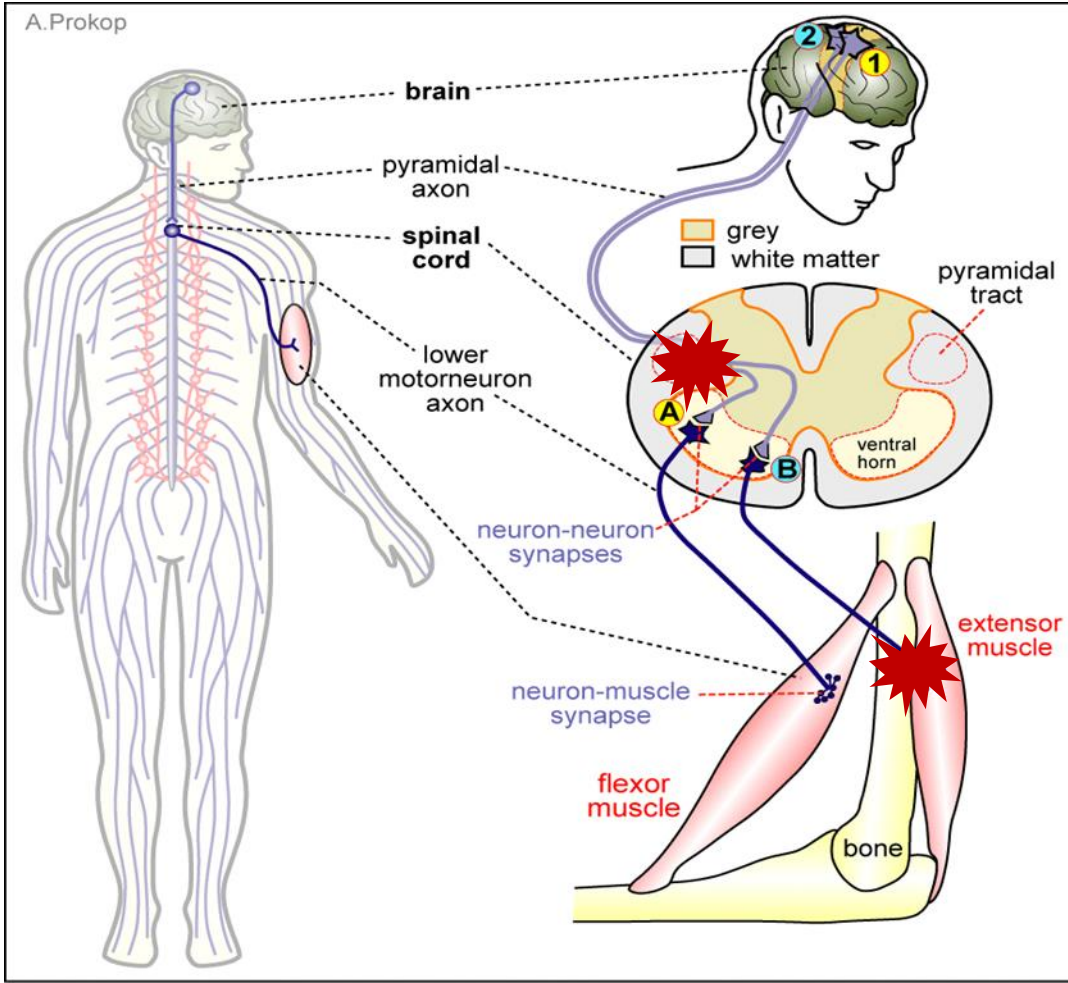
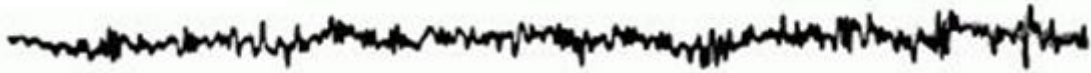
Old



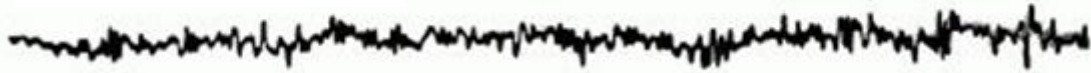
Brain Activity – Movement / Disability



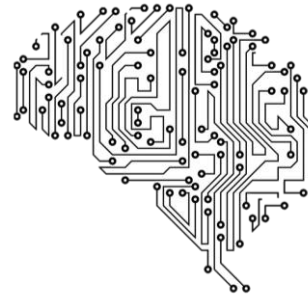
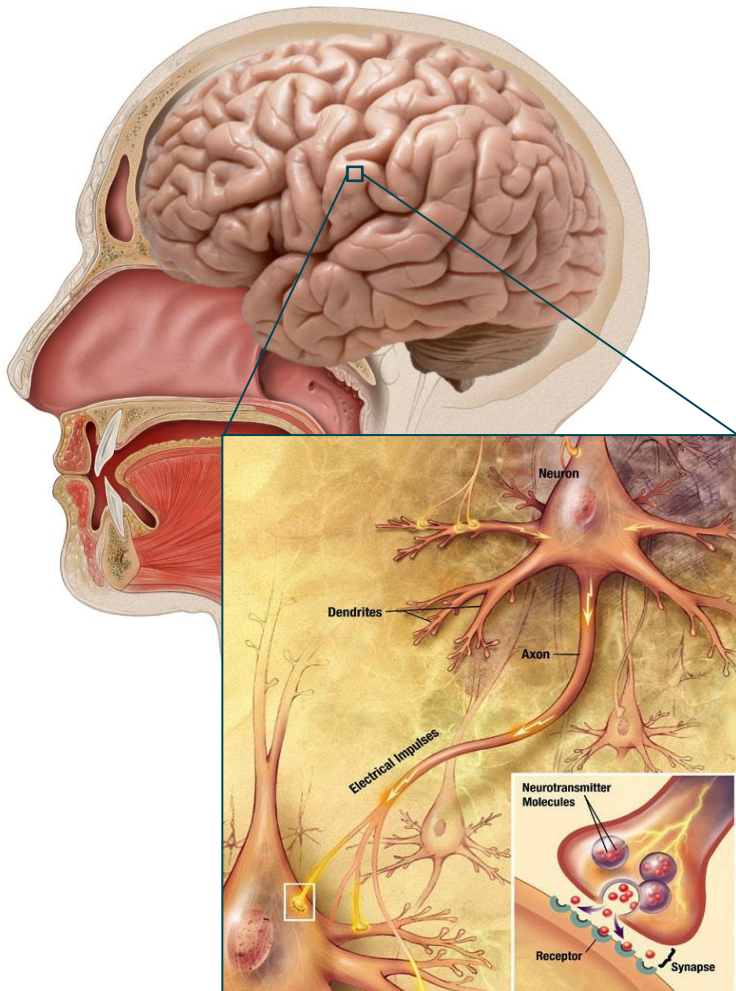
Healthy



Disabled



Brain Computer Interface Technology



1. Monitoring

Medical Device (for Disabled) / Mobility, XR, and Metaverse

2. Stimulation

Medical Device (Electroceuticals) / Brain Enhancement

Regulatory Status

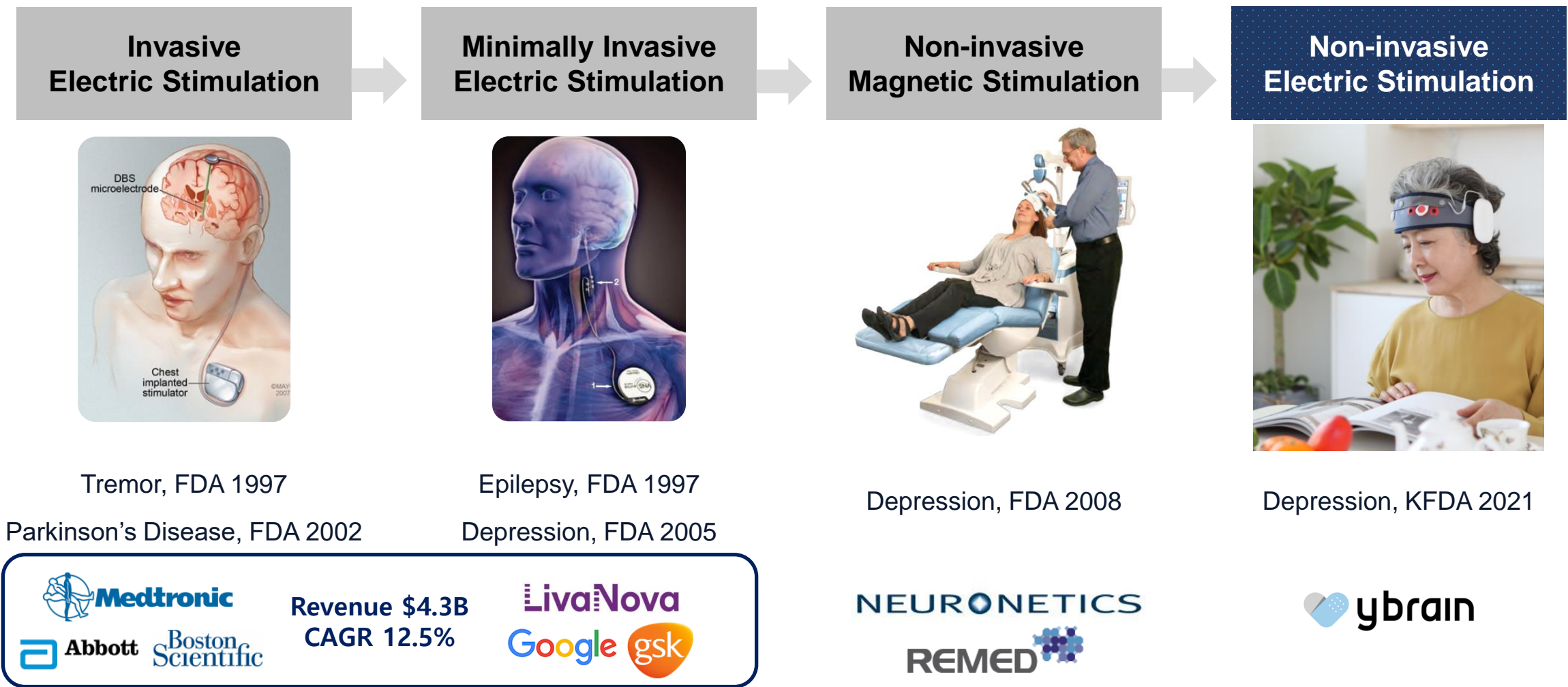
| Korea FDA | Classification | Class 1 | Class 2 | Class 3 | Class 4 |
|-----------|--------------------|----------|-----------------------------|---|-------------------------------------|
| | Gernerall Criteria | No Risk | Low Risk | Mid Risk | High Risk |
| | For BCI | | Non-Invasive BCI Monitoring | Non-Invasive BCI Stimulation | Invasive BCI Monitoring/Stimulation |
| US FDA | Classification | Class 1 | | Class 2 | Class 3 |
| | General Criteria | Low Risk | | Mid Risk | High Risk |
| | For BCI | – | | Non-Invasive BCI Monitoring/Stimulation | Invasive BCI Monitoring/Stimulation |

- A neurostimulation product that claims to improve memory, due to the risks to a user's safety from electrical stimulation.
- A product that claims to enhance a user's athletic performance by providing suggestions based on the results of relative lactic acid testing, when the product uses venipuncture to obtain the blood samples needed for testing. Such a product is not low risk because it is invasive (e.g., obtains blood samples by piercing the skin) and also because the product involves an intervention that may pose a risk to the safety of the user and other persons if specific regulatory controls are not applied (e.g., venipuncture may pose a risk of infection transmission).

Following such request, the Commission adopted the Commission Implementing Regulation (EU) 2022/2347 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose. The brain stimulators are reclassified in class III.

Invasive/Non-Invasive BCI (Stimulation) – Technology Development Trend

From Invasive to Non-invasive Stimulation Techniques for At-home Treatment



Source: Company Financials

Invasive/Non-Invasive BCI (Stimulation) – Recent FDA Approvals

Increasing # of Novel Indications including Cancer, Essential Tremor, Migraine, and ADHD

novocure

GBM, FDA 2011
NASDAQ listed



neuroConn

Research Device
Acquired by PE in 2014



kt NeuroSigma

ADHD, FDA 2019
\$13.4M funding (KT, etc.)



CEFALY

Migraine, FDA 2017
Acquired by PE in 2019



GALVANI
BIOELECTRONICS

Rheumatoid Arthritis
\$700M investment by Google Verily and GSK



CALA
HEALTH **SK** 바이오팜

Essential Tremor, FDA 2018
\$148M funding (J&J, SK, etc.)



theranica

Migraine, FDA 2019
\$41M investment by aMoon, etc.



electroCore

Migraine, FDA 2018
\$150M investment by Merck, etc.
NASDAQ listed



Understanding Healthcare System

Players of Health Care System

Receiver



- Patients
- Families of Patients
- Healthy people

Provider



- Physicians & Nurses
- Hospitals
- Drug & Device Suppliers

Financier



- Governments
- Insurance Companies

Types of Healthcare System

National Health Service

- Receivers served by government
- UK, Canada, and Sweden

National Health Insurance

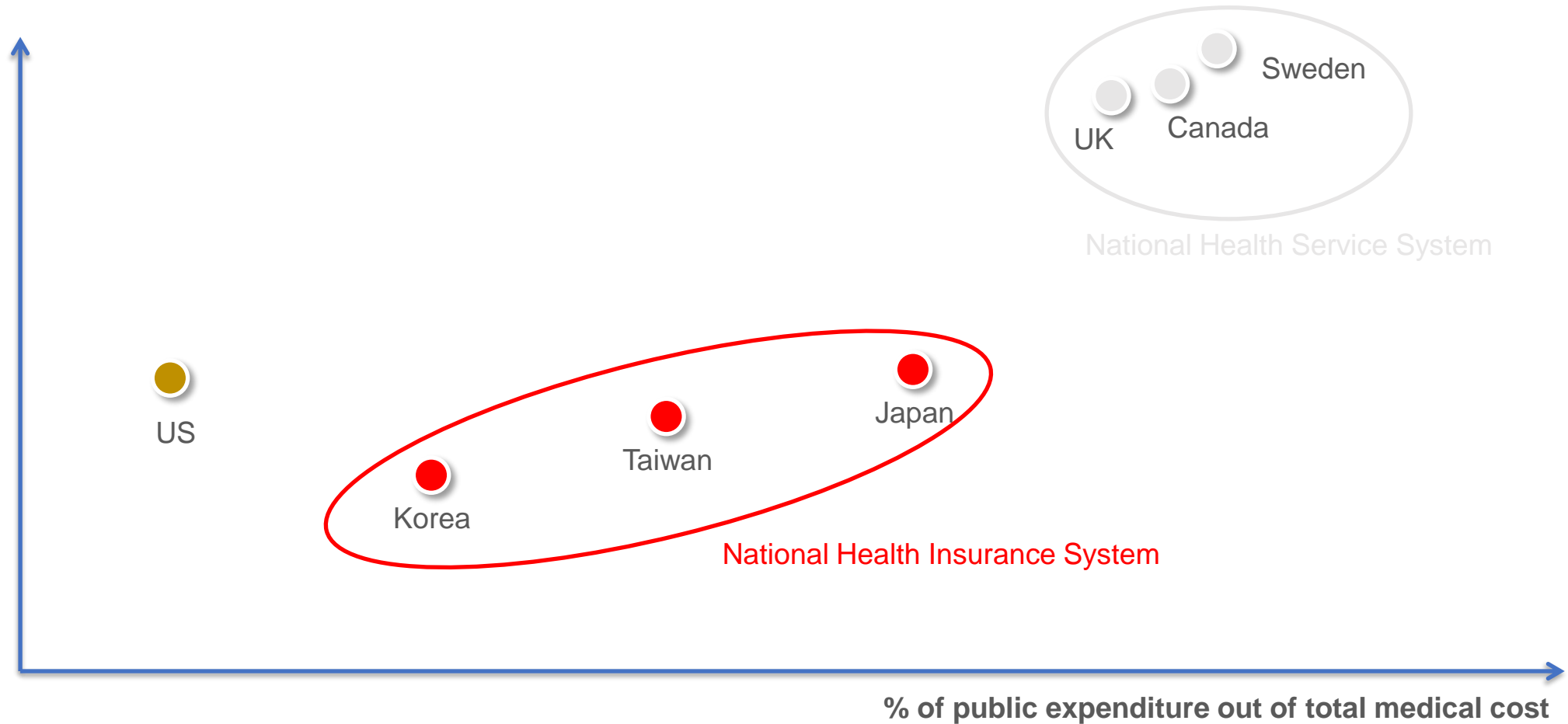
- Receivers served by private but insured by government
- Korea, Japan, and Taiwan

Free Market

- Receivers served by private & insured by private
- US (changing to National Health Insurance)

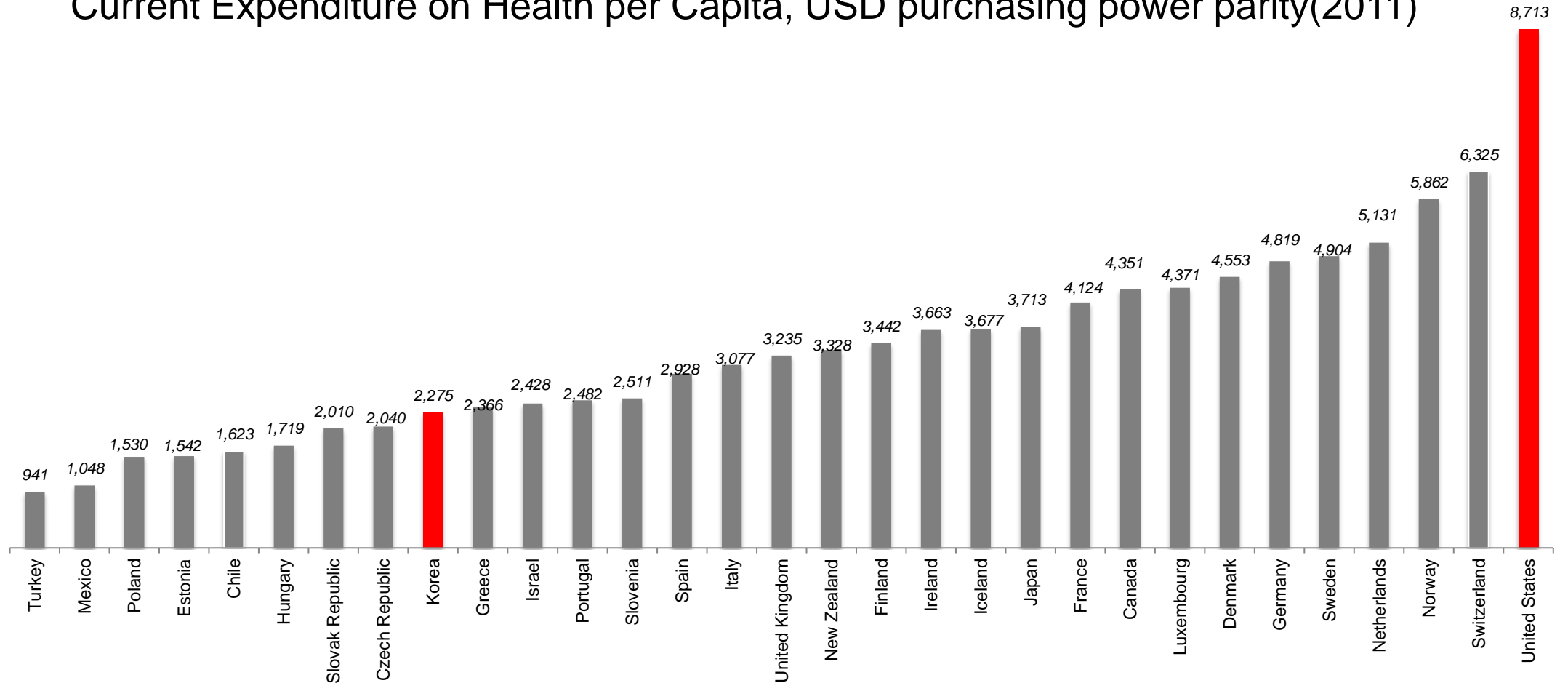
Types of Healthcare System

% of public hospitals(number of beds)



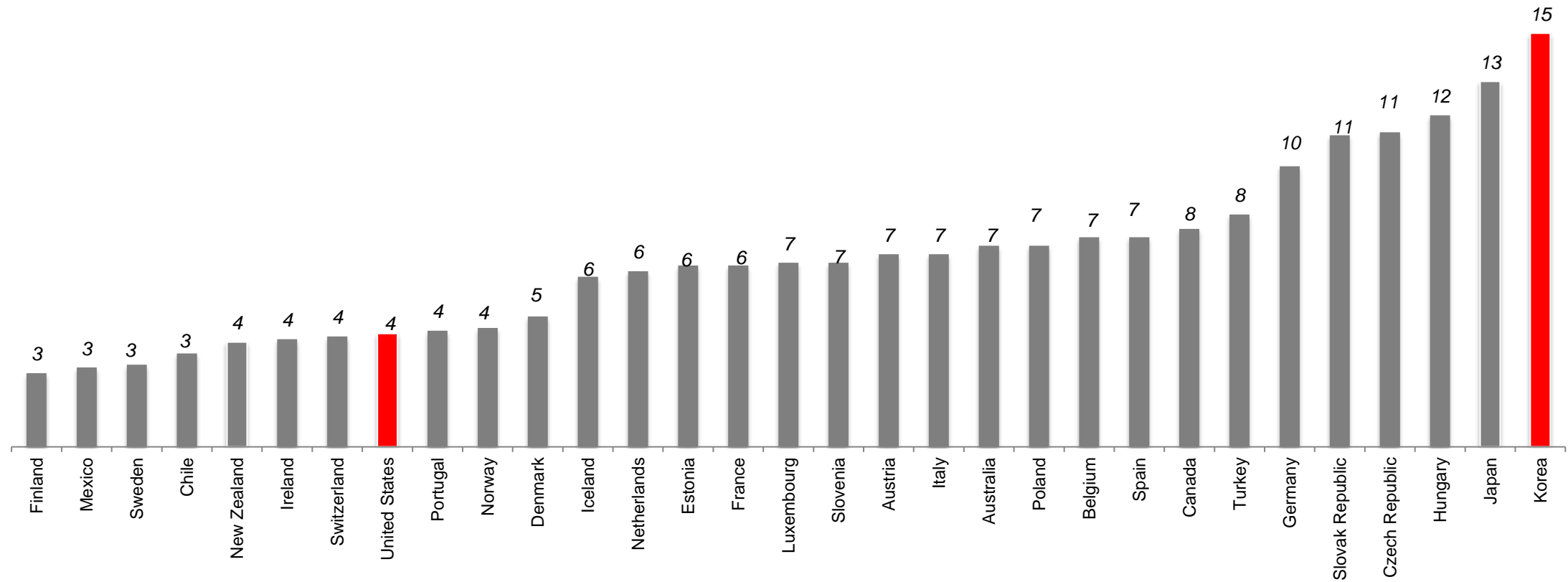
Healthcare Environment (Korea/US)

Current Expenditure on Health per Capita, USD purchasing power parity(2011)



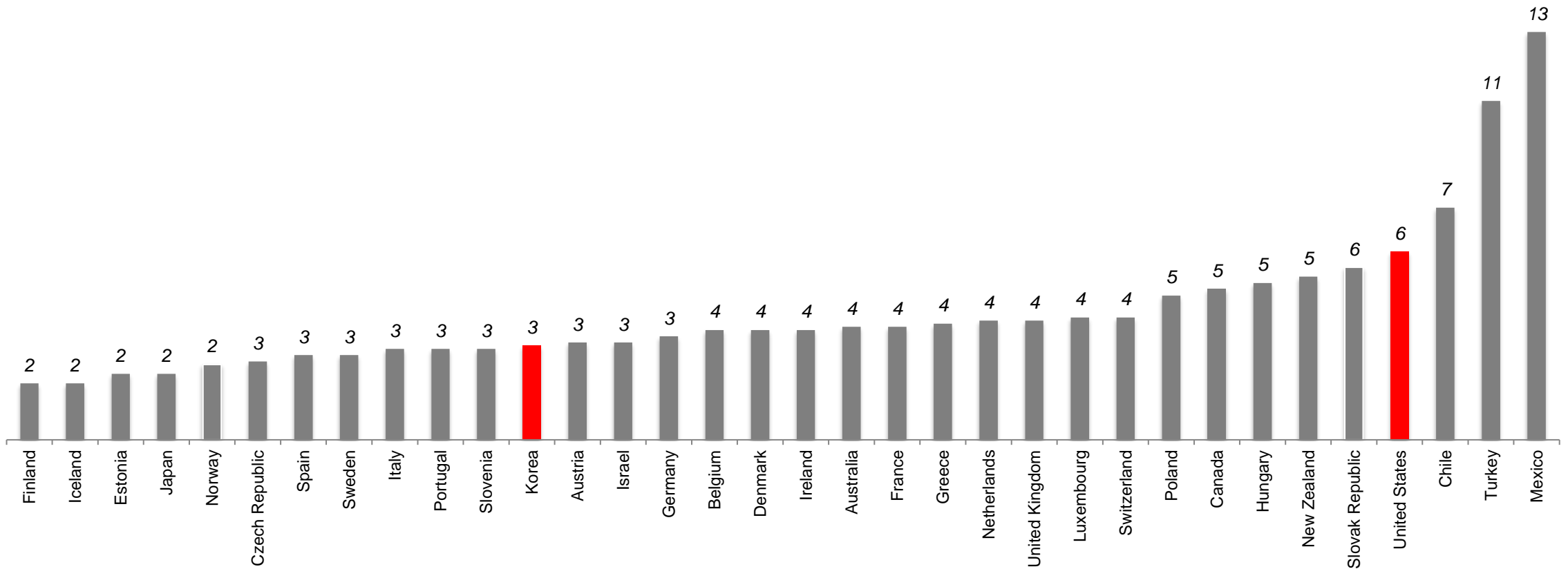
Healthcare Environment (Korea/US)

Doctors Consultation, Number per Capita (2011)



Healthcare Environment (Korea/US)

Infant Mortality, Death per 1,000 live Birth (2011)



Healthcare Environment (Korea/US)

‘Healthcare is Culture’

Number of Hospital Beds in Korea

| | |
|---------------------------|--------------|
| Asan Medical Center | 2,700 |
| Yeonsei University | 2,496 |
| Samsung Medical Center | 1,983 |
| Seoul National University | 1,792 |
| Seoul St. Mary’s Hospital | 1,356 |

Number of Hospital Beds in US

| | |
|--------------------|--------------|
| Cleveland Hospital | 1,400 |
| Johns Hopkins | 1,059 |
| Mayo Clinic | 794 |
| M.D. Anderson | 654 |

Healthcare Environment (Korea/US/Other Countries)

‘Healthcare is Culture’

| | Medical Cost (USD) | | % of Caesarean Section |
|---------|--------------------|-------------------|------------------------|
| | Normal Delivery | Caesarean Section | |
| Korea | 1,056 | 1,957 | 36.8% |
| US | 4,551 | 7,449 | 32.7% |
| Canada | 2,800 | 4,820 | 27% |
| Finland | 1,521 | 4,808 | 15.7% |
| Israel | 1,856 | 2,002 | 18.8% |

Healthcare Environment (Korea)

➔ Opportunities in Government-driven Innovation / Collaboration with Medical Society

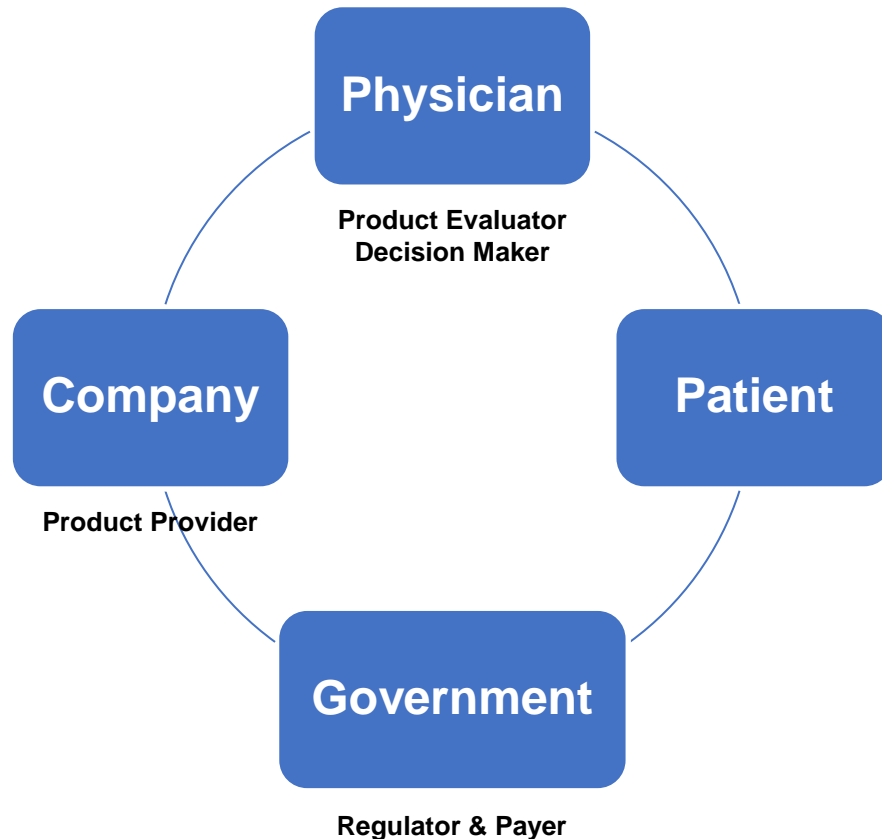


Healthcare vs. Consumer Product

Healthcare Product

Decision Maker \neq User

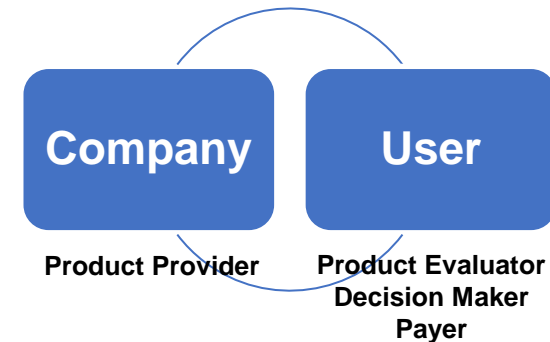
→ Credibility is important



Consumer Product

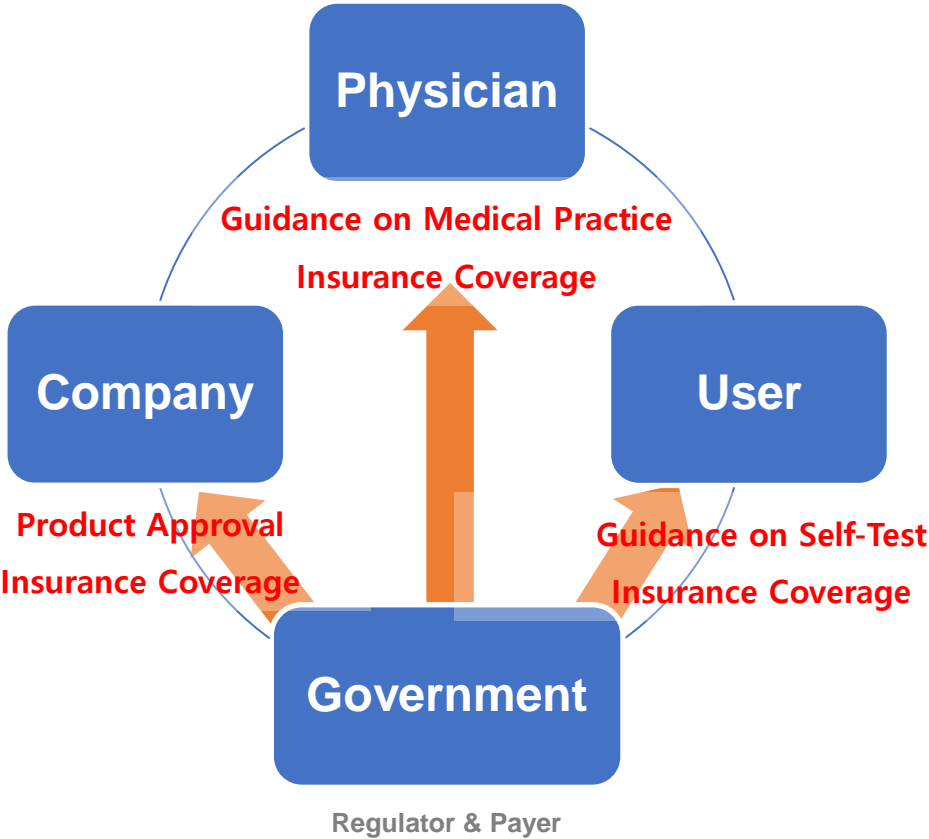
Decision Maker = User

→ Experience is important

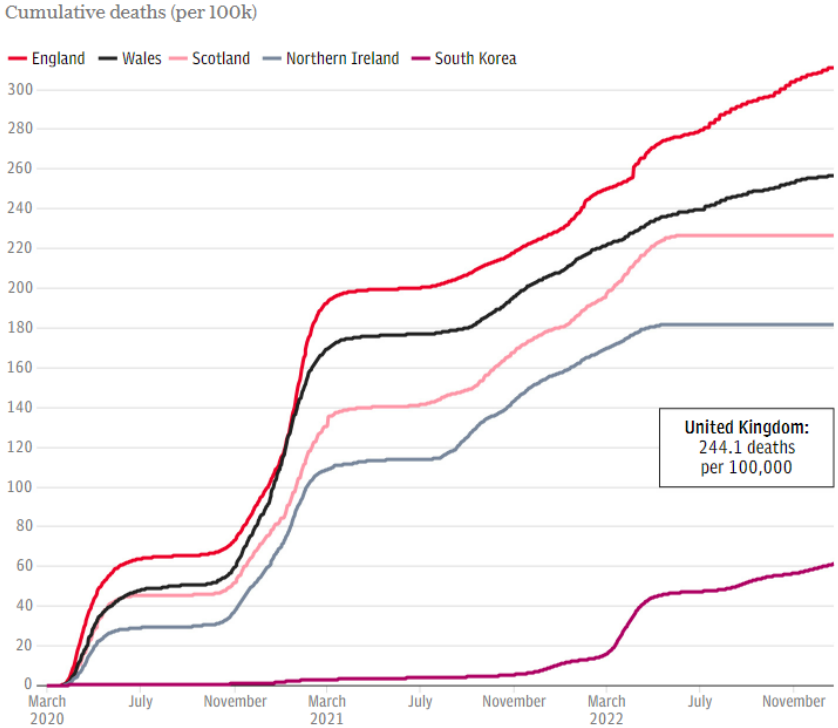
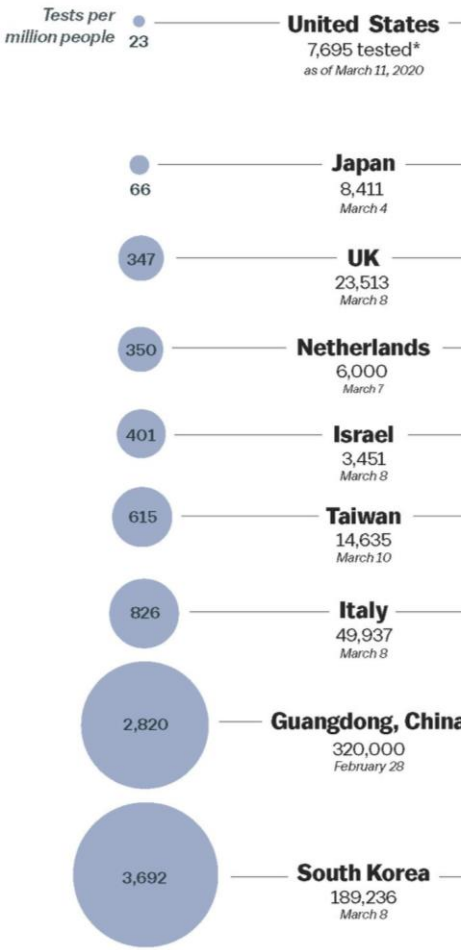


Government-driven Innovation during COVID-19 Pandemic

Government-driven Innovation



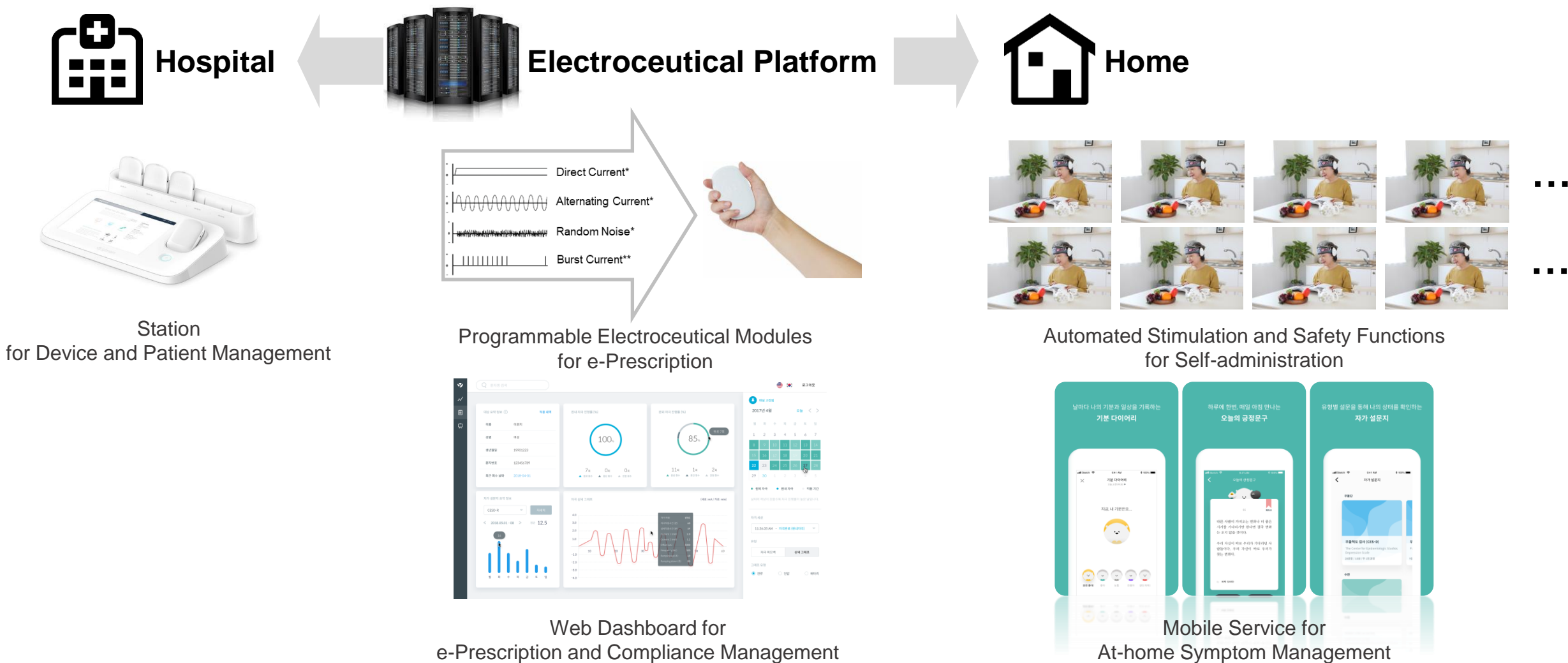
COVID-19 Test Cases and Cumulative Death



SOURCE: FINANCIAL TIMES ANALYSIS OF DATA FROM JOHNS HOPKINS CSSE, WORLD HEALTH ORGANIZATION, NATIONAL PUBLIC HEALTH AGENCIES OR MINISTRIES OF HEALTH

Non-Invasive BCI (Stimulation) – Clinic-to-Home Electroceutical Platform

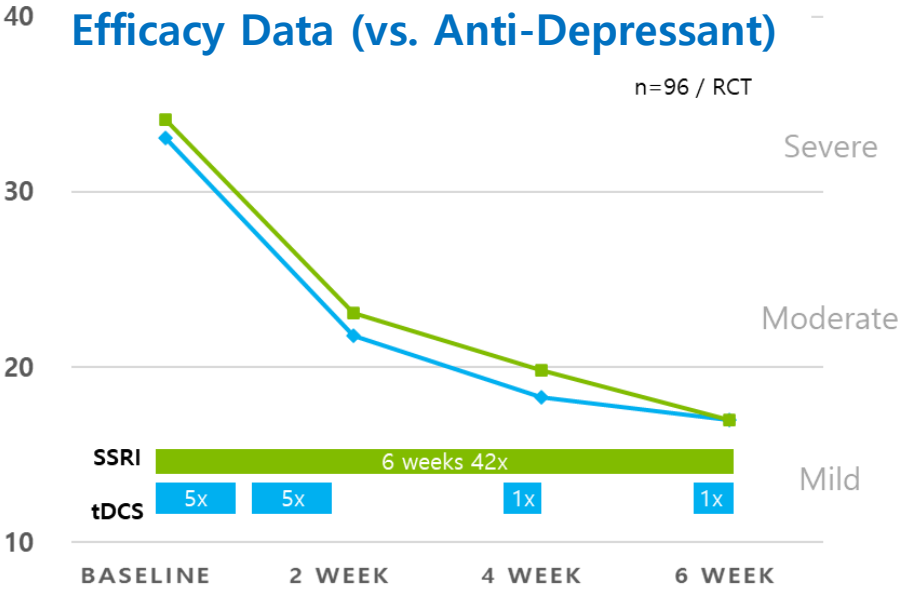
Electronic Prescription + At-home Self-administration + Remote Management



Non-Invasive BCI (Stimulation) – Pivotal Clinical Trial (Major Depressive Disorder)

Efficacy and Safety Proved by At-home Self-administration Pivotal Trial

→ First-in-Class Pre-Market Approval in this Industry



Efficacy Data (At-home Self-administration)

| | Remission @ week 6 (Ratio) | Remission @ week 6 (%) | 95% CI* |
|------------------------------|----------------------------|------------------------|---------------|
| Anti-depressant (Sertraline) | 7/14 | 50% | 23.04-76.96 |
| Electroceutical v1.0 | 6/12 | 50% | 21.09-78.91 |
| Electroceutical v2.0 (FA) | 35/61 | 57.4% | 44.06 ~ 69.96 |
| Electroceutical v2.0 (PP) | 27/43 | 62.8% | 46.73 ~ 77.02 |

1. Park et al. *Journal of Psychiatric Research*. 2020;127:42-47

Non-Invasive BCI (Stimulation) – Collaboration with Medical Society and Government

Neurostimulation Center Collaboration with University Hospitals



Academic Activities at Domestic/International Conferences



Industry Minister's Award and Certified Innovative Product



Media Coverage

Forbes / BBC / Euronews /

IEEE / Nature Biotechnology

Treating Depression With tDCS:
Startup Ybrain Aims for the Mainstream

The Korean company's consumer-friendly tDCS gadget could help this electric treatment catch on

By Eliza Strickland



Photo: Ybrain

Partnership with Domestic Pharma Companies



Collaboration with National Mental Health Centers



Non-Invasive BCI (Stimulation) – Recognition by Medical Society and Government

1st Approved Device + Notified Medical Practice + Official Treatment Guideline

「Medical Device Approval」 by the Ministry of Food and Drug Safety

April 2021

「Medical Practice」 notified by The Ministry of Health and Welfare

June 2022

「tDCS Treatment Guideline」 published
by Korean Brain Stimulation Society

February 2022

| | | | |
|----------------------|---|--|---|
| 제허 21-331 호 | | | |
| 의료기기 제조 허가증 | | | |
| (업 허가번호 : 제 4590 호) | | | |
| 구 | 번 | <input checked="" type="checkbox"/> 제조 / <input type="checkbox"/> 수입 | <input checked="" type="checkbox"/> 품목 / <input type="checkbox"/> 품목류 |
| 명 (제품명, 품목명, 모 명) | MINDO STIM+, 심리요법용 뇌전기자극장치, YMS-2018+ | 대류번호 (등급) | A16180.02 (3) |
| 모 양 및 구 조 | 별첨 | | |
| 주요 재 료 | 별첨 | | |
| 제 조 방 법 | 별첨 | | |
| 성 에 | 별첨 | | |
| 사 용 회 적 | 별첨 | | |
| 사 용 방 법 | 별첨 | | |
| 사용 시 주의사항 | 별첨 | | |
| 포 장 단 위 | 별첨 | | |
| 저장방법 및 사용기간 | 저장방법 : 별첨, 사용기간 : 별첨 | | |
| 시 험 구 격 | 별첨 | | |
| 제조(수입)업자 정보 | 제조(수입)업자 : (주)와이비리온, 대전광역시 유성구 죽동로 71 2층 202호(죽동) 제조원 : 상동 | | |

6. 경두개직류자극술을 이용한 주요우울장애 치료

가. 기술명

- 한글명 : 경두개 직류자극술을 이용한 주요우울장애 치료
- 영문명 : Treatment of Major Depressive Disorder using Transcranial Direct Current Stimulation

나. 사용목적

- ### ○ 우울 증상 개선

다. 사용대상

- 경증 및 중등증 단극성 비정신병적 주요우울장애 환자

라. 시술방법

- 좌측 배외측진전두엽, 우측 배외측진전두엽에 패치를 부착하고 모듈을 이용하여 착용 상태와 자극설정(①주기 1일 1회, 매주 5 ~ 7회, 6주, 총 30 ~ 42회, ②전류 1.5mA ~ 2mA, ③시간 30분)을 인식하여 직류 전류 자극을 진행함

마. 평가 유예 대상 의료기기 목록

- (주)와이브레인, 심리요법용뇌용전기자극장치(YMS-201B+외 1건)
(제허 21-331호, 2021.4.26.)

바. 평가 유예 기간

- 2022년 6월 1일부터 2024년 5월 31일까지

경도개직류자극 치료 지침

주요 우울장애



Non-Invasive BCI (Stimulation) – At-Home Depression Treatment Platform

Non-Pharmaceutical + At-Home Self-administration + Remote Management

| | Remission @ week 6 (Ratio) | Remission @ week 6 (%) | 95% CI* |
|---------------------------------|----------------------------------|------------------------------|---------------|
| Anti-depressant (Sertraline) | 7/14 | 50% | 23.04-76.96 |
| Electroceutical v1.0 | 6/12 | 50% | 21.09-78.91 |
| Electroceutical v2.0 (FA) | 35/61 | 57.4% | 44.06 ~ 69.96 |
| Electroceutical v2.0 (PP) | 27/43 | 62.8% | 46.73 ~ 77.02 |



Non-Invasive BCI (Stimulation) – Collaboration with Medical Society and Government

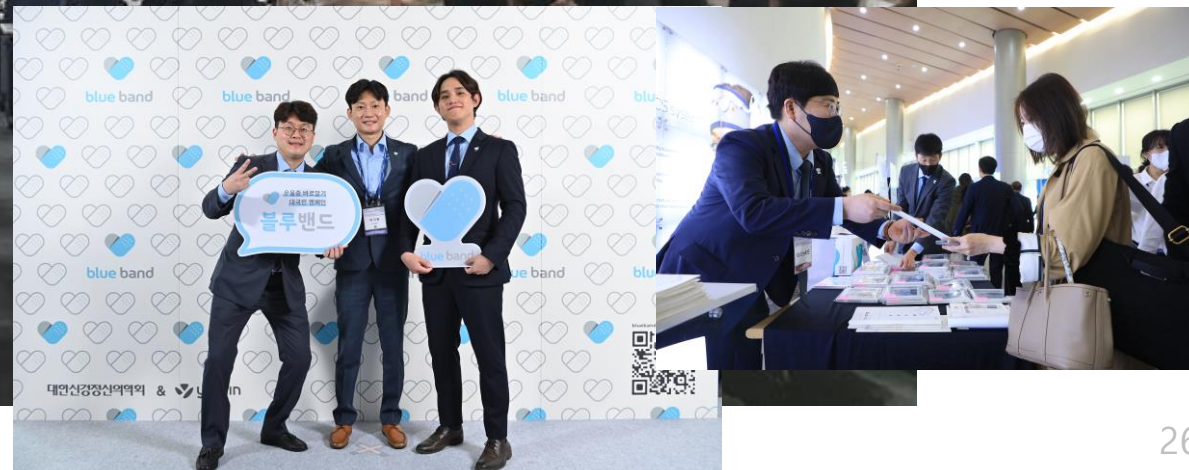
Nation-wide Campaign for Depression Education & Treatment – BLUE BAND



Non-Invasive BCI (Stimulation) – Collaboration with Medical Society and Government



와이브레인, 신경정신의학
회 추계 학회 블루밴드 캠페인
부스 참가 < 다국적제약/의료기기 > 단신 < 기사
본문 - 의학신문
(bosa.co.kr)



Non-Invasive BCI (Stimulation) – Collaboration with Medical Society and Government



Non-Invasive BCI (Stimulation) – Collaboration with Medical Society and Government

KOR | EN

대한신경정신의학회

HOME | LOGIN | JOIN

학회소개

학술행사

자료실

게시판

전공의

회원검색하기 >

학회사무국 안내

knpa1945@hanmail.net

09:30 ~ 17:30

토,월,공휴일 휴무

대한신경정신의학회와 와이브레인이 함께하는

‘우울증 바로 알기 대국민 캠페인’

블루밴드

blue band

대한신경정신의학 & ybrain

바로가기

JKNA

Journal of Korean Neuropsychiatric Association

신경정신의학회 pISSN 1015-4817 / eISSN 2289-0963

저널검색하기

논문투고시스템

PSYCHIATRY INVESTIGATION

pISSN 1738-3684

eISSN 1976-3026

저널검색하기

논문투고시스템

故 임세원 교수님을 추모합니다

47년간의 헌신은 온전히

동료와 후배를 위한 고귀한

덕분에 우리와 함께

우리 함께 살아야 하는 뜻

이전입니다.

온라인사전등록

전공의 심포지엄

개원의 심포지엄

임상뇌파워크숍

지도전문의 교육

인권교육(시설장)

법률자문

진료 및 임상에 대한 법률자문 및 사례를 제공합니다.

뉴스레터

학회의 최신소식을 전달합니다.

윤리강령 및 규정

학회에 조직된 윤리인권위원회 규정과 학회의 윤리선언

공지사항 / 업체 연구 동향

2022년도 정신건강증진시설시설장인권교육과정 교육 안내

지도전문의 교육 이수확인 방법

(ECNP) 2022 참가 지원 신청자 모집 공고

2024년도 회기 회장 임후보 공고

학회일정

대한신경정신의학회 2022년도 추계학술대회

대한신경정신의학회 2023년도 춘계학술대회

대한신경정신의학회 2023년도 추계학술대회

blue band

우울증 평가 및

치료 인증병원

우울증 치료는 꼭 정신건강의학과

전문의와 상담하세요.

대한신경정신의학

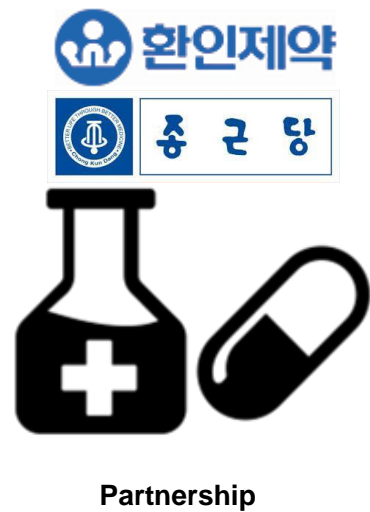
대한정신건강재단

30 cm * 30 cm

28

Non-Invasive BCI (Monitoring/Stimulation) – Psychiatry Clinics

Diagnosis / Treatment / Management Services through ONE Platform



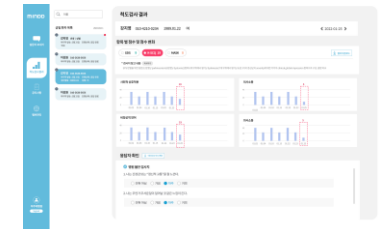
Co-Promotion with Partnerships



Bio-signal Analysis for Diagnosis



Electronic Questionnaires for Diagnosis



Electroceutical Platform for At-home Treatment



“Expecting Great Synergy with Existing Sales and Marketing Resources”
- Pharmaceutical Company A, Sales Director Y

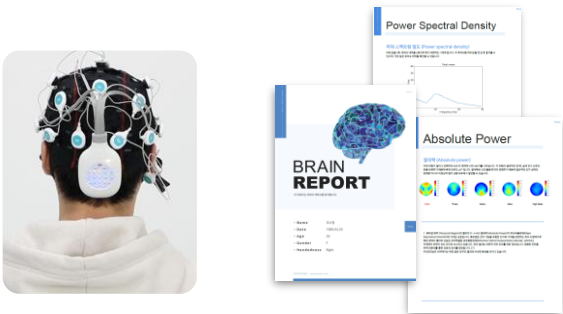
“Safe, Effective, even Profitable Solution. Will Become an Important Solution for Psychiatry Hospitals and Clinics”
- University Hospital B, Prof. C

“Most Ideal Electroceutical System”
- Brain Stimulation KOL, Prof. M

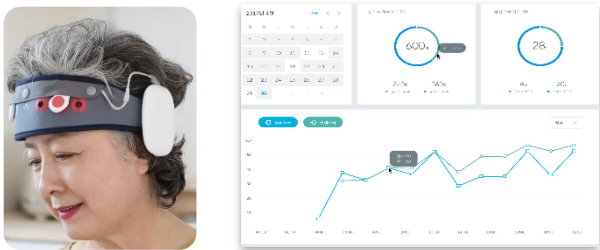
Non-Invasive BCI (Monitoring/Stimulation) – Psychiatry Clinics

Currently 30%+ Psychiatry Clinics are using Ybrain's BCI Platform

Diagnosis
(Reimbursed)



Treatment
(Listed Medical Practice / Cash-only)



Diagnosis and Management
(Reimbursed)



of Clinics

287

139

491

Usage

200,000

90,000

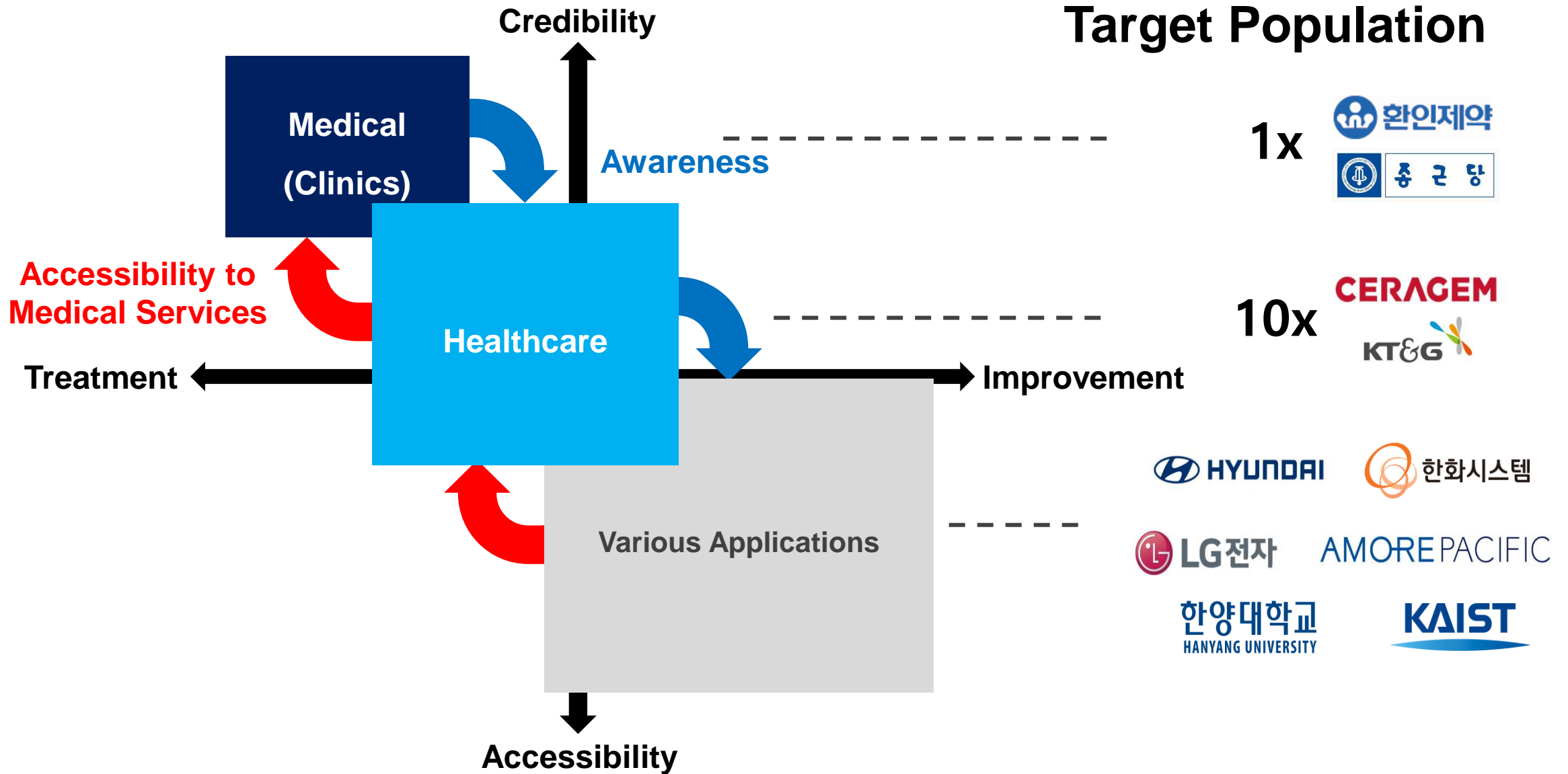
440,000

8,000+ per month

8,000+ per month

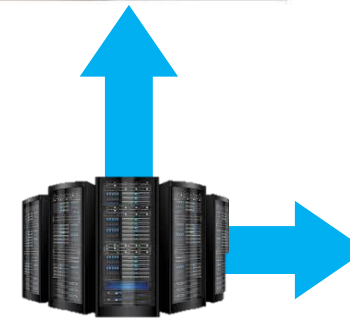
30,000+ per month

Non-Invasive BCI (Monitoring/Stimulation) – Expansion Strategy





Personal Mobility BCI combined with Electric Wheelchair / Gait-assist Robot



Source: Hyundai Motors

Non-Invasive BCI (Monitoring) – Driver Monitoring BCI for Safety

BCI combined with Driver Management / Autonomous Driving System

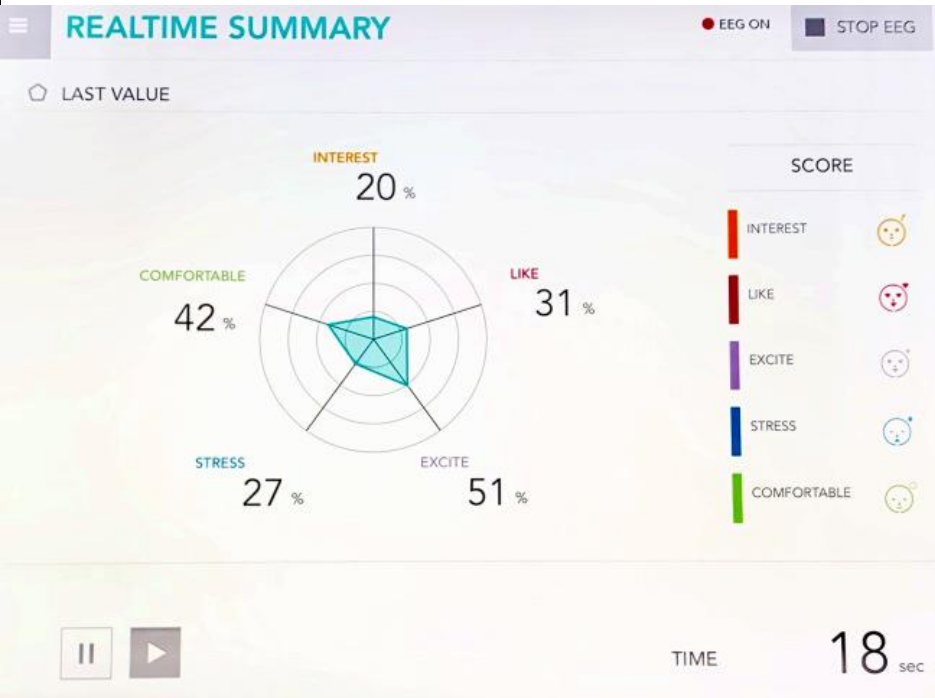


Non-Invasive BCI (Monitoring) – Wearable BCI for Epilepsy Patients

BCI combined with the use of anti-seizure medication



BCI combined with personalization programs for perfumes and cosmetics



Non-Invasive BCI (Monitoring) – Earbud BCI for Mental health and Sleep



BCI combined with sound therapy for mental health and sleep



Commercialization Cases in South Korea

Non-Invasive BCIs

Monitoring



AMOREPACIFIC



Stimulation



Invasive BCIs

Monitoring/Stimulation

?

Invasive BCI (Monitoring/Stimulation) – Mobility BCI for Disabled

마비 환자가 체내이식 수술을 통해 생각만으로 로봇을 신체의 일부처럼 움직이는 것을 목표로 설정



ISO/IEC JTC1 SC43 BCI for International Standardization

ISO와 IEC 두 기관의 BCI 국제표준 공동 제정을 위한 위원회 → 의장국 중국 / 화웨이 적극 참여



WG1 – Foundational Standards

WG2 – BCI Applications

WG5 – BCI Data

1. **Hardware Specifications**
2. **Connection APIs**
3. **Data Acquisition Protocol** between devices, software, or servers
4. **Data Formats** for devices, software, or server-based services
5. **Data/Signal Processing Methods** for specific applications

Summary

- 뇌의 전기회로적 특성을 활용하는 BCI는 측정, 진단, 치료에 활용 가능
- 치료 분야에서는 3등급/4등급 의료기기 중심으로 글로벌 상용화 사례가 증가하고 있음
- 국내에서는 규제 및 의료 시장 특성을 고려한 병원 중심의 재택 치료용 3등급 의료기기 임상, 허가, 시장 진입 성공 사례가 존재하며 그 외 측정/진단 분야 2등급 의료기기 개발 사례 다수 존재
- 국내 4등급 BCI 상용화 사례는 아직 없으나 의료기기 규제를 고려한 기술 개발, 목표 적응증 확보를 위한 임상 설계 및 실행, 의료 시장 이해도 및 표준화 활동 등을 통한 국제 경쟁력 확보 및 상용화 기회가 있음



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