



**Digital biomarkers as a new source of clinical data  
to aid clinical trials and treatment**

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# ABOUT LUNDBECK

## Vision

We strive for global leadership in  
**psychiatry** and  
**neurology**  
by improving the lives of patients

## Principles

We are **focused,**  
**passionate** and  
**responsible**



For more than 70 years, we have been at the forefront of neuroscience research and our development of pioneering treatments makes a difference to patients worldwide.

## Key disease areas



Depression



Schizophrenia

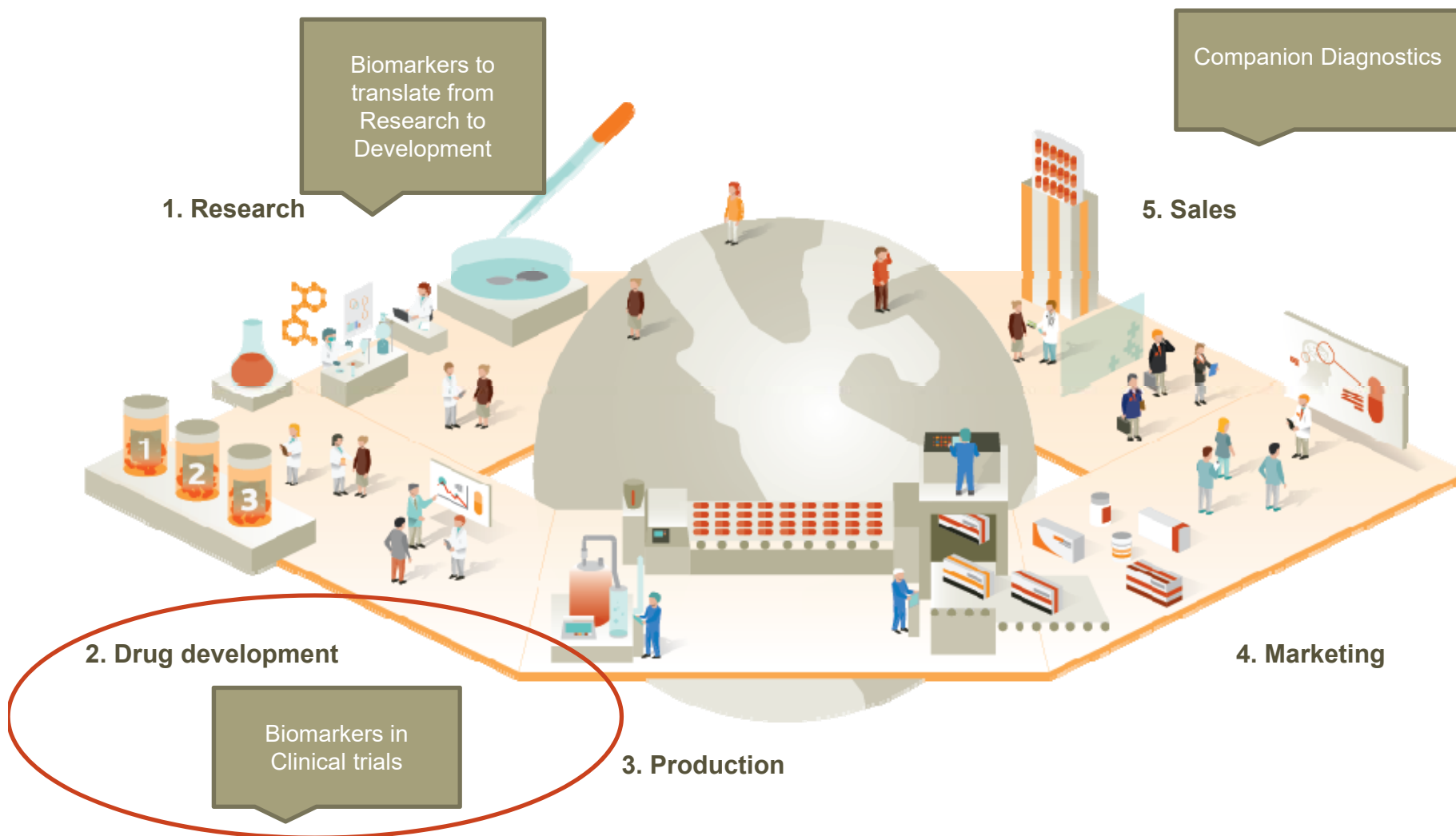


Alzheimer's disease



Parkinson's disease

# LUNDBECK'S VALUE CHAIN



# Psychiatry and Neurology

## Regulatory required assessments of disease

- ★ Clinical scales to assess disease
  - ★ Validated assessment scales for specific diseases
  - ★ Clinician ratings / Patient self-ratings (care-giver)
  - ★ Often high placebo response



- ★ Primarily assessed when patient is seen by the clinician
  - ★ Subjective assessments
  - ★ Assessed e.g. every 2 weeks looking back at the period since last visit

- ★ Can we measure more objectively and more continuously with minimal (or without) burden for the patient?
  - ★ Use of technology used in daily living?
  - ★ Keep the patient group in mind



# PARKINSON'S DISEASE



**6**million

people worldwide are living with Parkinson's disease.

Parkinson's disease affects 1% of the population over the age of

**60**

Parkinson's disease is the

**2<sup>nd</sup>**

most common neurodegenerative disorder.



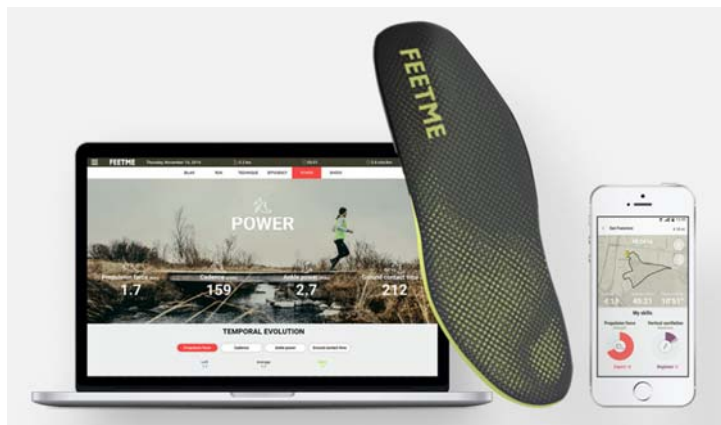
**"Everything will be different if you treat Parkinson's like an old friend, rather than an enemy."**

**Sheng Kanghua**  
Living with Parkinson's disease

# Parkinson's Disease: abnormal movements

## ★ DTU Open Innovation X

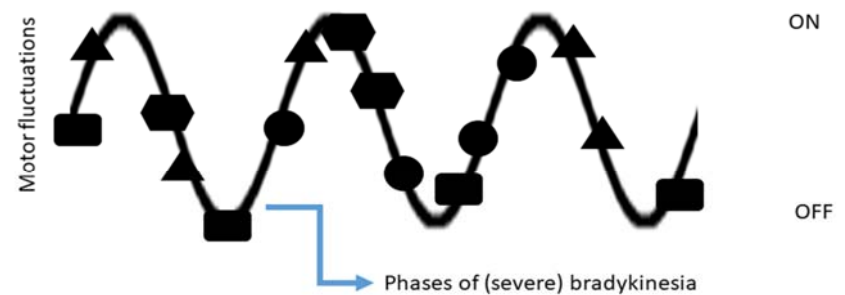
- ★ Skin contact patch
- ★ Wristband
- ★ Socks
- ★ Wearable ankle device
- ★ **Shoe soles**
- ★ Cutlery
- ★ Mat
- ★ Shirtsleeve



## ★ Collaboration with academia



● Wearable position sensors



● Different types of movements performed during the motor fluctuation cycles (walking, sit-to-stand movements, turning, teeth brushing, ironing, etc.)

# DEPRESSION



**300**million

people worldwide are estimated to live with depression.

Cognitive symptoms (difficulty concentrating, forgetfulness and/or indecisiveness) appear

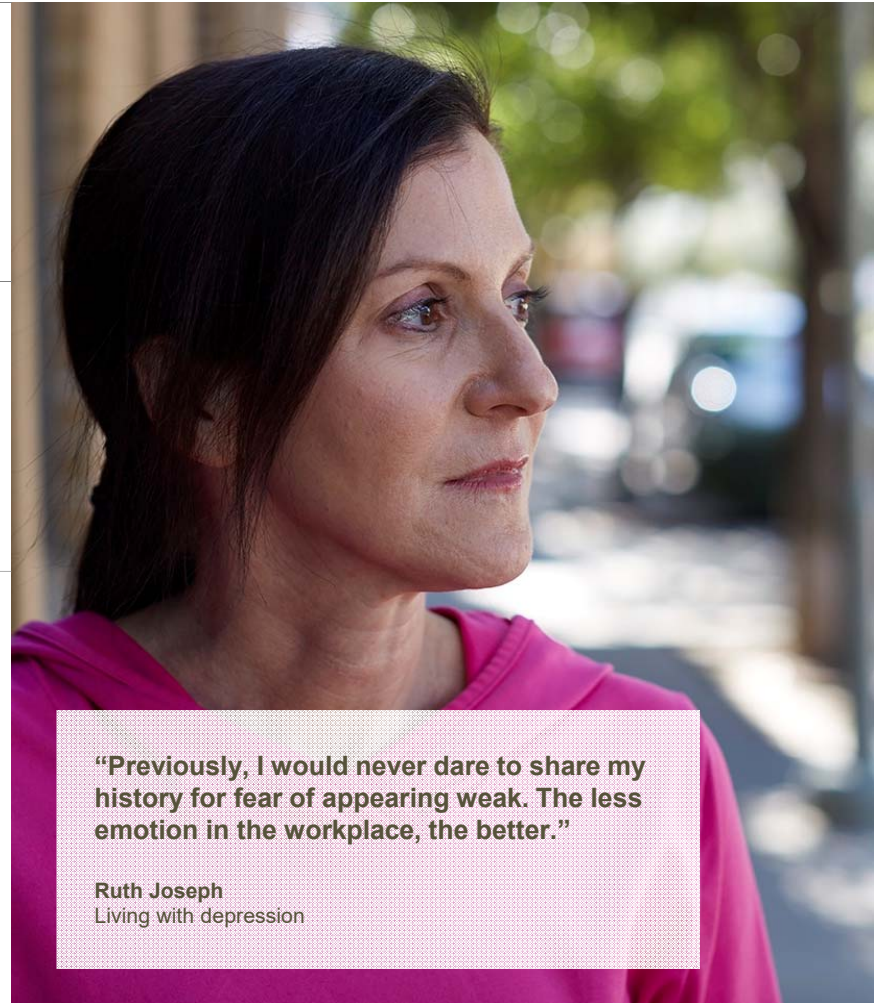
**94%**

of the time during major depressive episodes.

One study found that up to

**65%**

of individuals suffering from depression rate their condition as being severely disabling.












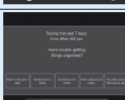
**“Previously, I would never dare to share my history for fear of appearing weak. The less emotion in the workplace, the better.”**

**Ruth Joseph**  
Living with depression

# Depression: Cognition



- ★ The THINC Task Force has developed a simple assessment tool
- ★ the objective is to help physicians screen for cognitive dysfunction in their patients with depression.

Test	Cognitive domain	
 <b>Spotter:</b> Choice Reaction Time test (CRT)	Psychomotor speed	
 <b>Symbol Check:</b> N-back memory task	Memory Executive function Attention/concentration	
 <b>CodeBreaker:</b> Digit Symbol Substitution Test (DSST)	Executive function Processing speed Attention/concentration	
 <b>Trails:</b> Trail Making Test B (TMT-B)	Executive function	
 <b>PDQ-5D:</b> Perceived Deficits Questionnaire (PDQ)	Attention/concentration Planning/organisation Retrospective memory Prospective memory	

- ★ The tool is comprised of a questionnaire (PDQ-5), and four traditional cognitive assessments which has been gamified for computer-based administration.
- ★ The THINC-it® cognitive screening tool is available for use in research settings
- ★ iPad, Android tablet, Windows PC and Mac OSX



# Digital biomarkers: opportunities



## Improved medical treatment

- Objective assessments
- Assessments over longer timespans and in real-life settings

## Help patients regain possibilities

- Greater insight into own disease
- Active participation in own treatment



## Broader acceptance of patients

- Part of treatment (e.g. game for children with ADHD)



## More help for affected families

- Greater insight into disease
- Possibility for following the course of disease and the treatment more closely

# Digital biomarkers: challenges

★ Keep the patients in mind



# Digital biomarkers: challenges



DATA



INSIGHT

## Regulatory authorities requirements



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



# PROGRESS | IN MIND