

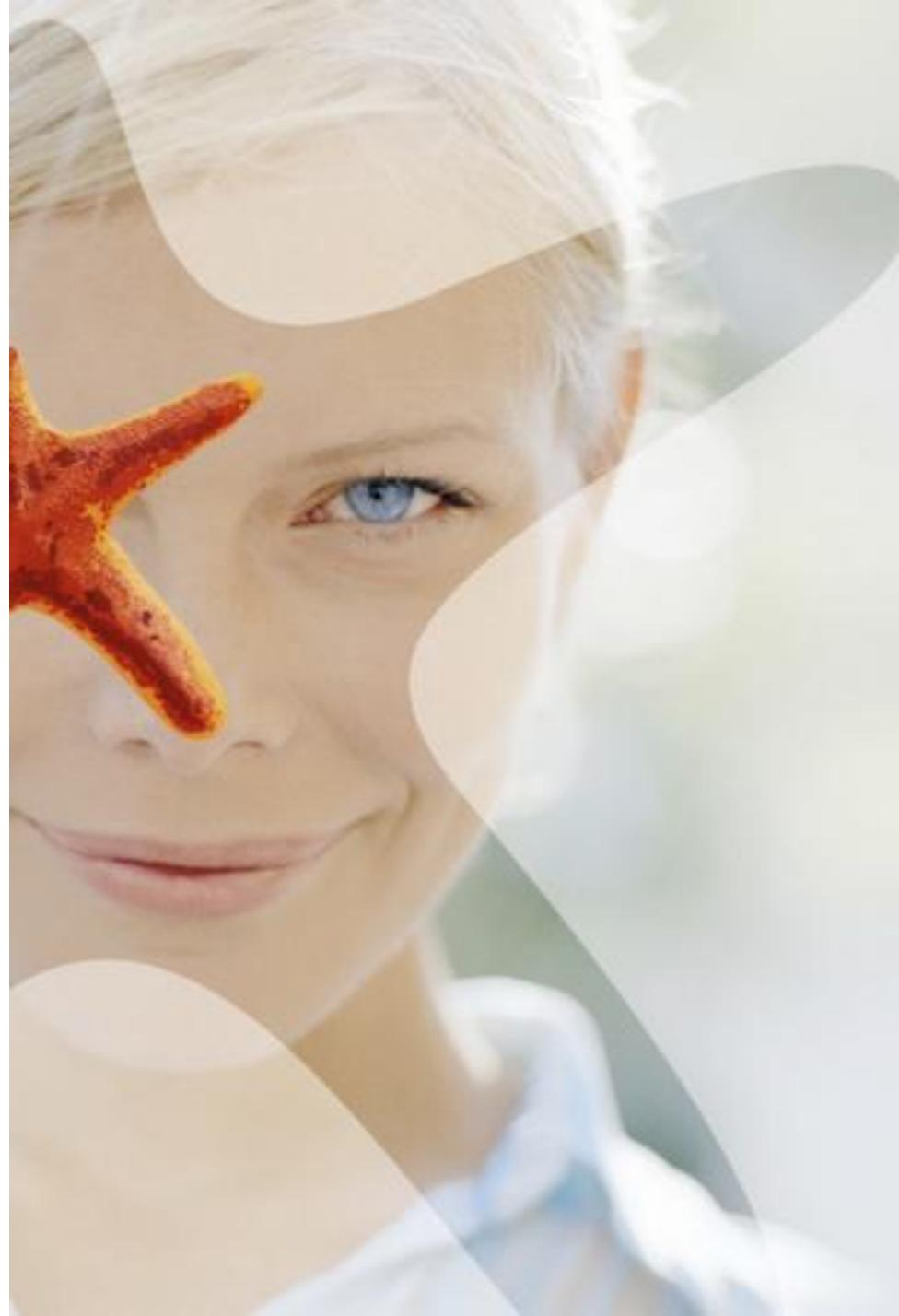
H. LUNDBECK A/S

8. November, 2011

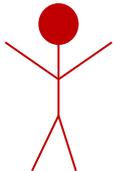
IFPMA

Research in brain disorders

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Agenda

1. Setting the stage 
2. What is the problem? 
3. What can we do about it? 

Brain disorders are the most prevalent diseases in Europe

Brain disorders are the most prevalent of all diseases in Europe.

More people suffers from depression and anxiety than diabetes mellitus and the average patient is more costly.

Brain disorders are Europe's primary healthcare challenge of the 21st century

Has to become the no. 1 priority in Eu health care !

	Prevalence estimate, %	No. of persons affected, million
Alcohol dependence	3.4	14.3
Drug dependence (opioid & cannabis)	0.4-2.2	2.4
Psychotic & bipolar disorders	2.1	8.0
Major depression	6.9	30.3
Panic and phobias	12.5	49.5
GAD, OCD, PTSD	3.5-6.3	19.5
Somatoform disorders	4.9	20.4
Eating disorders (anorexia & bulimia)	0.3-1.4	1.5
Personality disorders ^a (borderline & dissocial)	1.3	4.3
Childhood/adolescent ^b disorders incl. autism	1.6	6.0
Mental retardation	1.0	4.2
Sleep disorders ^c	7.32	30.3
Dementias ^d	1.2	6.3
Total	38.2%	164.8

WHO 2004, The Global Burden of Disease: 2004 Update

Wittchen et al. 2011 ECNP/EBC Report 2011

Sobocki et al. 2007, European Psychiatry

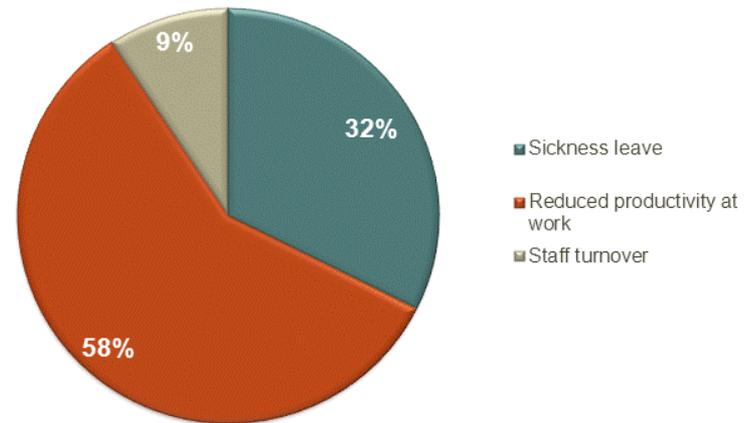
Norlund et al. 2001, J Int Med & Jönsson 2002, Diab

Table adapted from Wittchen et al. 2011 ECNP/EBC Report

The total medical healthcare costs are substantial

- ★ The total cost of Brain disorders has recently (2011) been estimated at **€798 billion**
- ★ Drug cost is less than 3 % of all costs
- ★ Sick leave counts for almost 1/3 of all cost in relation to depression
- ★ Reduced productivity at work is estimated to be the greatest part of all costs in depression

Depression: Cost of lost productivity
UK Study



Cost of depression by cost item
Sweden, 2005

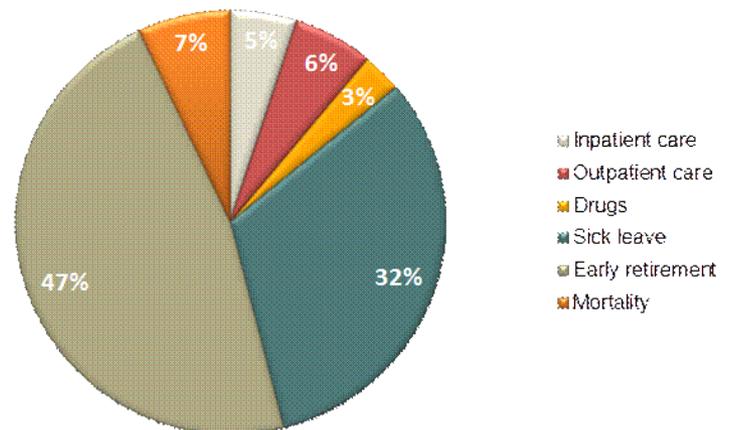


Figure 1: Sainsbury 2008

Figure 2: Sobocki et al. 2007, European Psychiatry
Gustavsson et al. 2011, EBC 2011, Eur Psychopharm

The Burden and unmet needs in Brain disorders

The burden of Brain disorders

- ★ According to the World Health Organization, more than 700 million patients suffers from Brain disorders. They account for some 11% of the global burden of disease.
- ★ Depression alone is expected to represent the single largest disease burden by 2030.

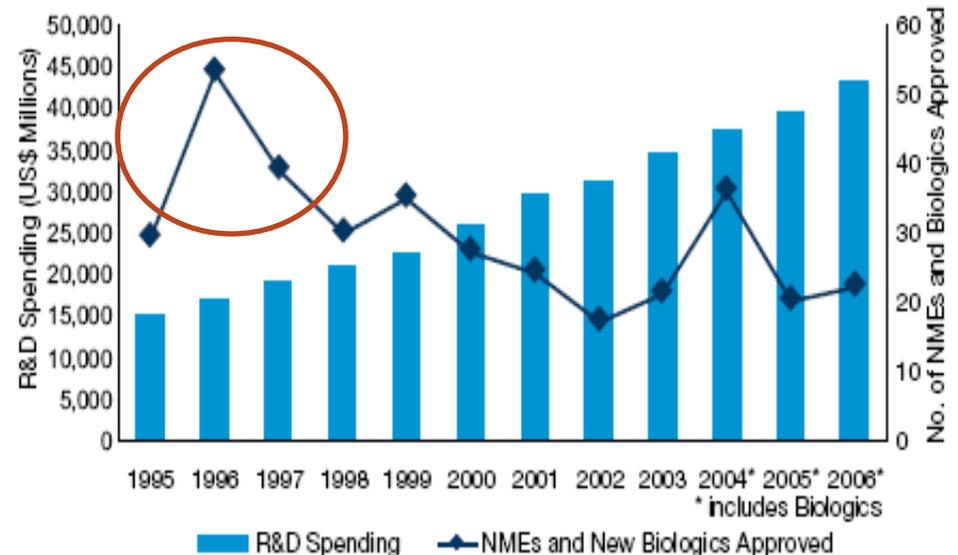
Unmet needs in Brain disorders, e.g.:

- ★ 75% of patients with alcohol dependence relapse within the first year.
- ★ Control of schizophrenia symptoms and delay of disease progression
- ★ Neuroprotection in Parkinson's and Alzheimer's

The pharmaceutical industry business model is under pressure

- ★ Trend that the number of new drugs are declining
- ★ Costs for developing new drugs continue to increase
- ★ Pharma incentive systems and profitability under pressure
- ★ Progress in basic science is not translated to medical innovation and benefits to patients

Figure 2: R&D spending has soared but the number of NMEs and biologics approved by the FDA is down



Sources: FDA/CDER Data, PhRMA data, PricewaterhouseCoopers analysis

Note: Data on R&D spending for non-PhRMA companies are not included here, because they are not available for all 11 years

Even greater challenges within Brain disorders

Longer time to develop new drugs

★ At an average of 13 years, the development time for medicines within psychiatry is longer than for other disease areas.

Greater failure rate

★ The failure rate for medicines in Brain disorders are higher than that for other disease areas and many medicines fail late in the development process – at Phase 3 or even at registration – leading to particularly high financial losses .

Companies are de-prioritizing Brain research

Several pharmaceutical companies have dis-continued activities in Brain disorders. In depression the situation is becoming critical.

Major CNS players

GlaxoSmithKline

February 2010 announces plans to withdraw from pain and depression discovery research with the closure of major facilities in Italy and the UK

Johnson & Johnson

March 2010 announces plans to pull out of schizophrenia, bipolar disorder, depression and anxiety

Astra Zeneca

Eli Lilly

Forest

MSD

July 2010 announces the closure of six research operations in Denmark, Germany, the Netherlands and Scotland, with no CNS research left in EU

Lundbeck

Pfizer

Abbott

September 2010 announces it will eliminate 800 positions in the Netherlands and in Germany with limited CNS research left in EU

Novartis

Sanofi-Aventis

Wyeth

A healthcare crises ahead

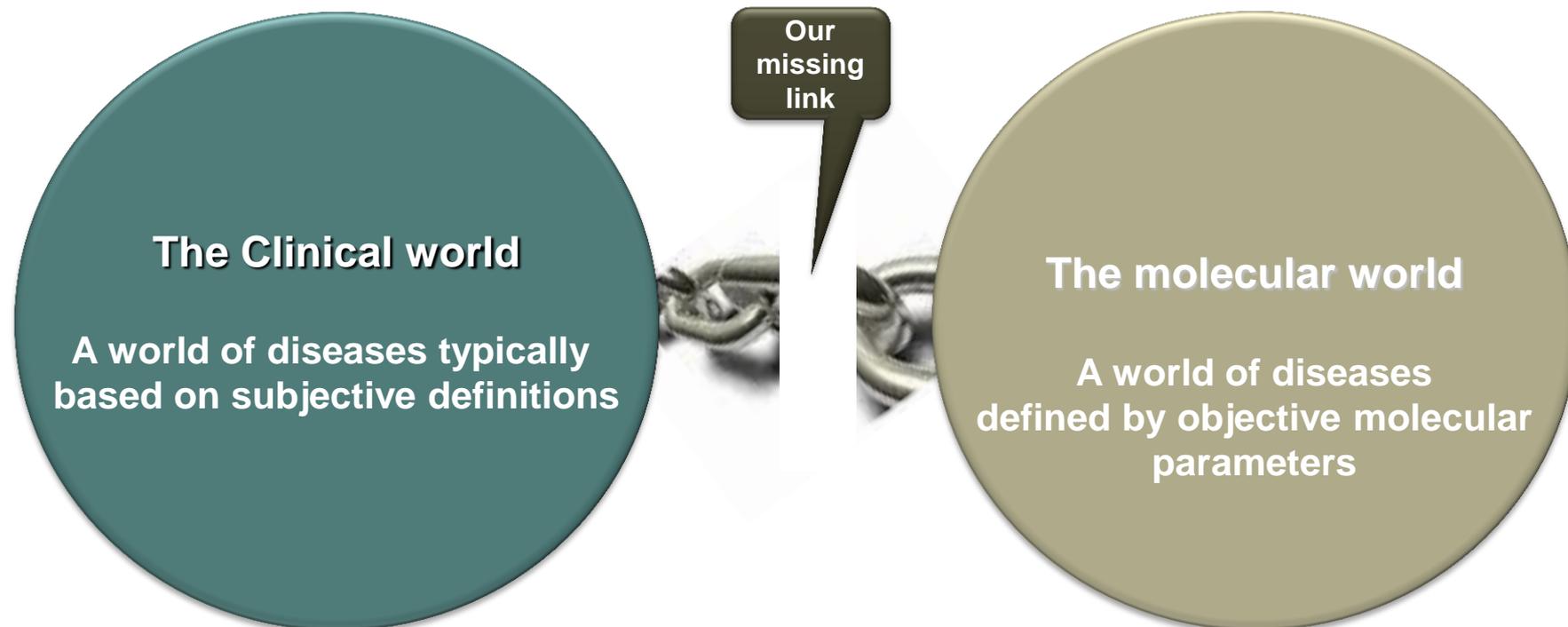
- ★ Political awareness on the healthcare and R&D challenges start to increase.
- ★ The current situation on antimicrobial resistance has shown, what happens if innovation and new drugs are not rewarded.
- ★ A similar situation will very likely appear within Brain diseases, if the situation is not addressed.



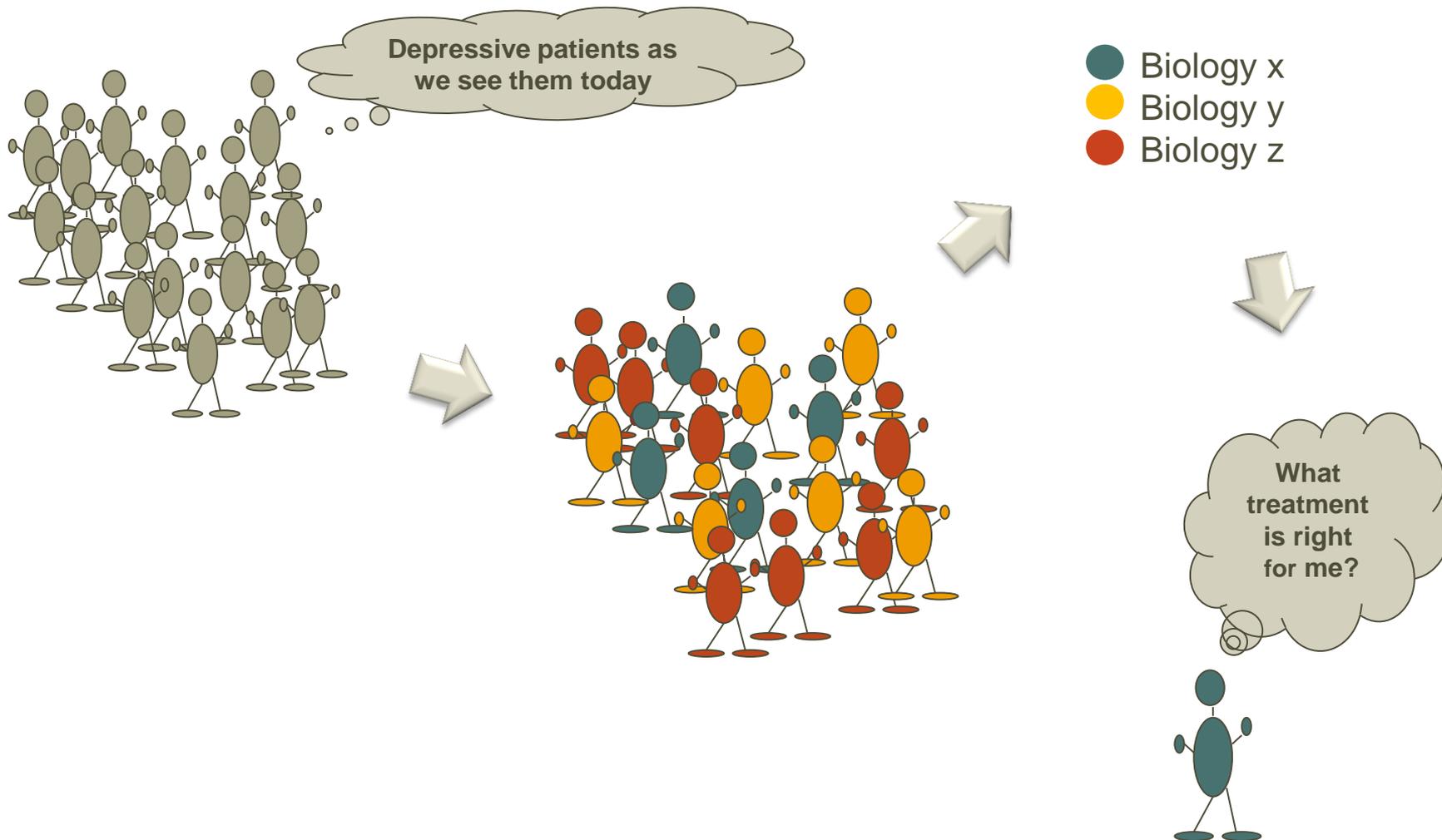
What is the problem?

- ★ Brain disorders are not prioritized politically
- ★ There continue to be a strong stigma around Brain disorders, which needs to be tackled
- ★ The approach from a health care providers point of view is not integrated or sufficiently holistic – they don't see the total costs
- ★ Limited research in Brain disorders
- ★ Lack of clinical tools
- ★ Incentive systems are insufficient
- ★ Regulatory demands are a barrier

Translational medicine



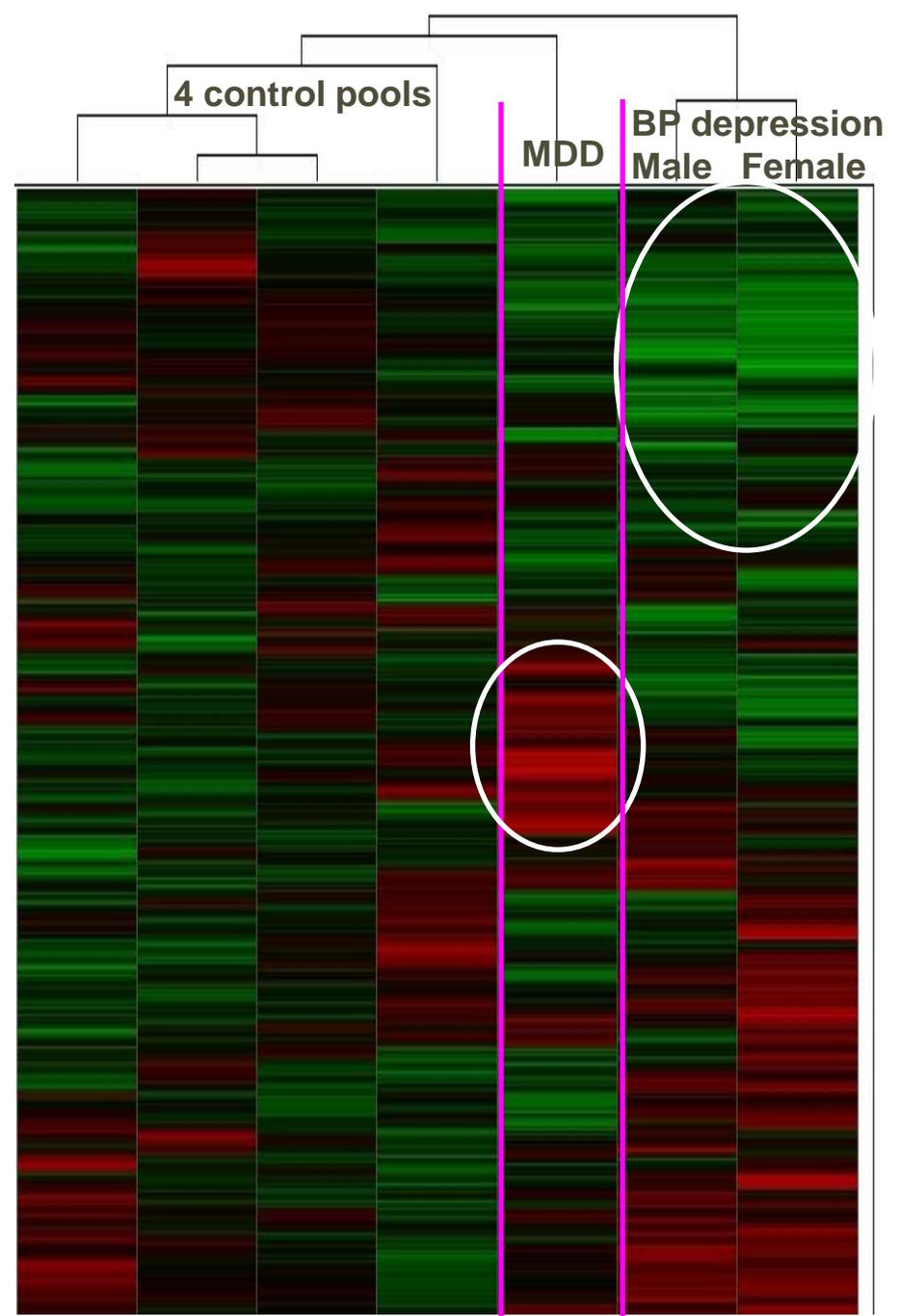
What we would like to offer



Scanning of activity level of all genes

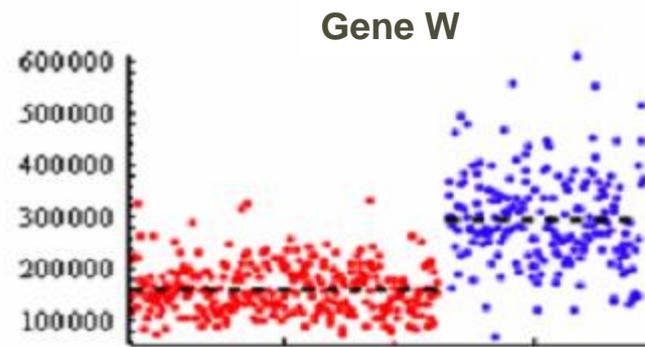
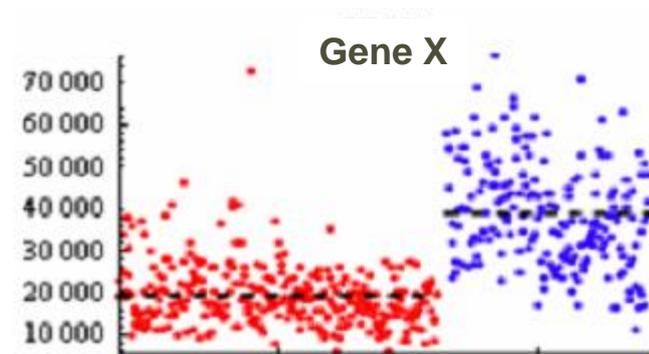
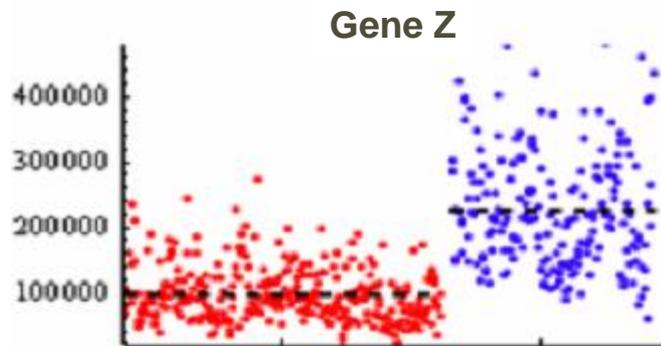
- ★ Severely depressed are different from controls and cluster together
- ★ Bipolar patients are most distinct from control

All detectable transcripts on genome wide Illumina microarray



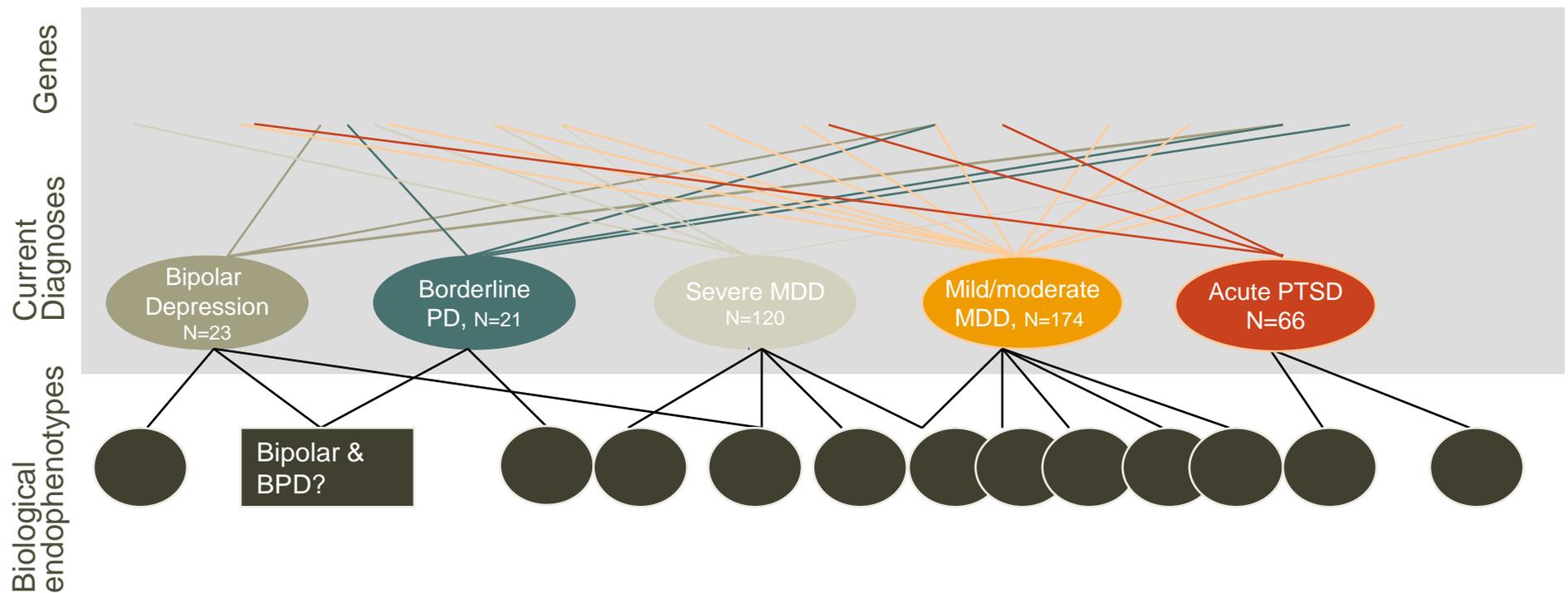
Transcriptional changes in Severe Depressed patients

- patients
- controls



Patient segmentation based on gene transcription data

Current biological signatures based on in-house data



Solutions – I – Working together

- ★ The society is facing huge healthcare challenges in relation to brain disorders. Only if society and industry join forces in Public Private Partnerships (PPP) can these challenges be addressed.
- ★ IMI (Innovative Medicine Initiative) is a unique and first of its kind public private partnership where cooperation between academia, the European Commission, SMEs, Regulators and the Pharma industry has changed the understanding and perspective of public private partnerships within life science
- ★ Pooling resources, experiences and knowledge across different sectors has shown its unique value and great future potential.
- ★ Important experiences have been collected and learned through IMI and these leanings should be brought into future PPP's (Horizon 2020)

Solutions – II – Scientific focus and Incentives

- ★ Focused research on elucidating disease biology for brain disorders will lead to:
 - ★ Identification of new targets and biomarkers
 - ★ Reclassification of brain diseases

Critical for new drugs to be invented

- ★ Development of new tools for evaluating effects of new drugs

- ★ Development of incentive structures rewarding future innovation, in the area of brain disorders