

**International Society of CNS  
Clinical Trials and Methodology  
5<sup>th</sup> Annual Meeting**

**George Gharabawi/Garibaldi, President ISCTM  
Washington DC, March 3<sup>rd</sup>, 2009**

Founded in 2004 as an independent not-for-profit multidisciplinary organization devoted to addressing clinical, regulatory and methodological challenges that arise in the development and clinical use of CNS therapeutic agents

ISCTM achieves its objectives through partnering with experts from industry, academia, governmental, non-governmental agencies and the public

Session dedicated to Dan Blevins, an ISCTM  
founding member with significant contribution to the  
society and to CNS research

# ISCTM Contribution to CNS Clinical Research

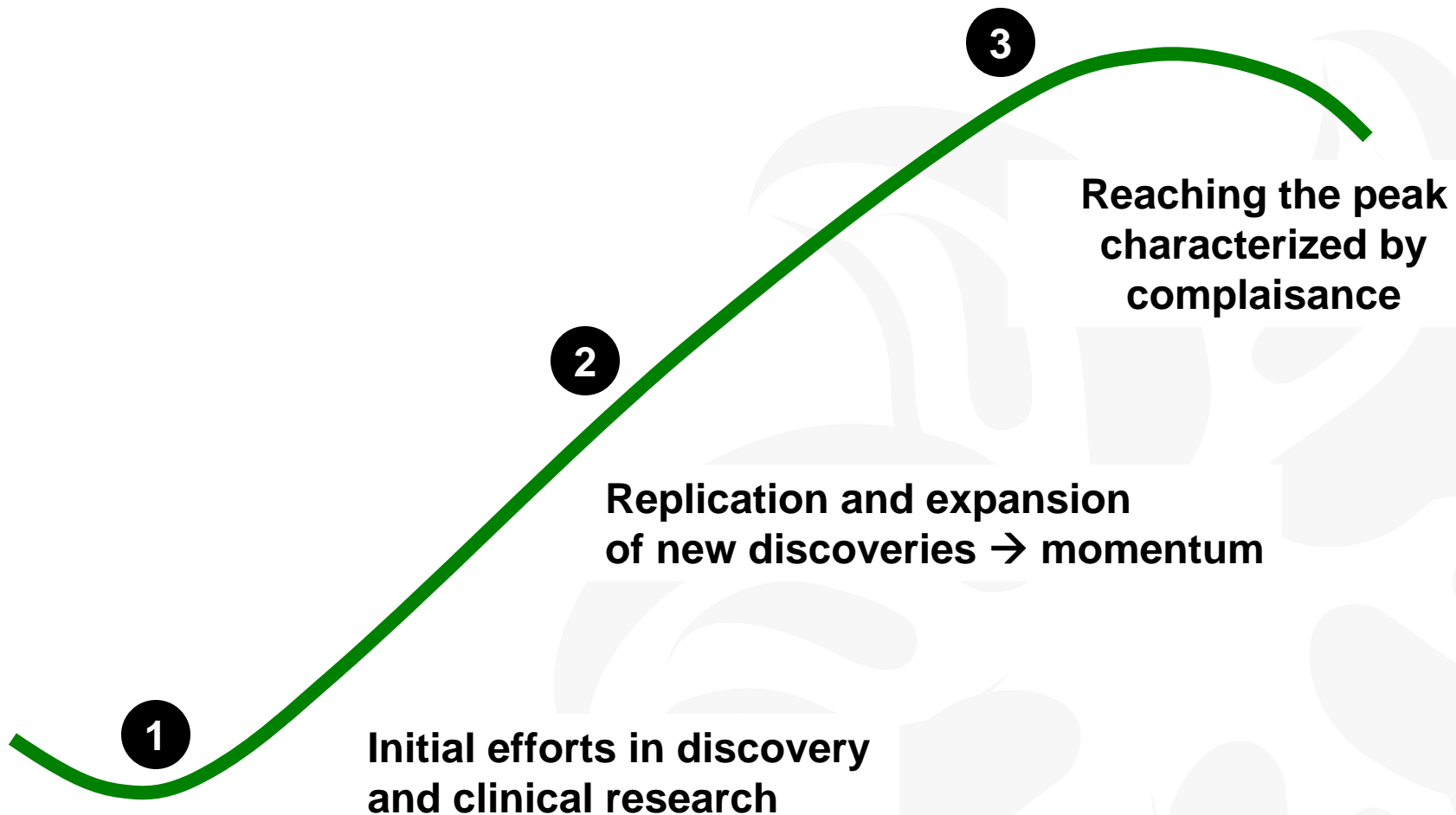
- Long-term trials in psychiatry
- Use of biomarkers
- Cognition in schizophrenia
- Treatment resistance
- Neuroprotection in Parkinson's
- Failed trials in schizophrenia

- MCI/AD, AD progression
- Parkinson's nonmotoric symptoms
- Negative symptoms of schizophrenia

- Dose selection
- Research in developing countries
- Post approval trials
- Attrition rate

- Neuropathic pain
- Devices
- Patient reported outcomes
- Suicidality with Ads
- Science and policy

# What if CNS is reaching the end of an S-Curve?



# The Dynamic Of Change

The internet changes our lives

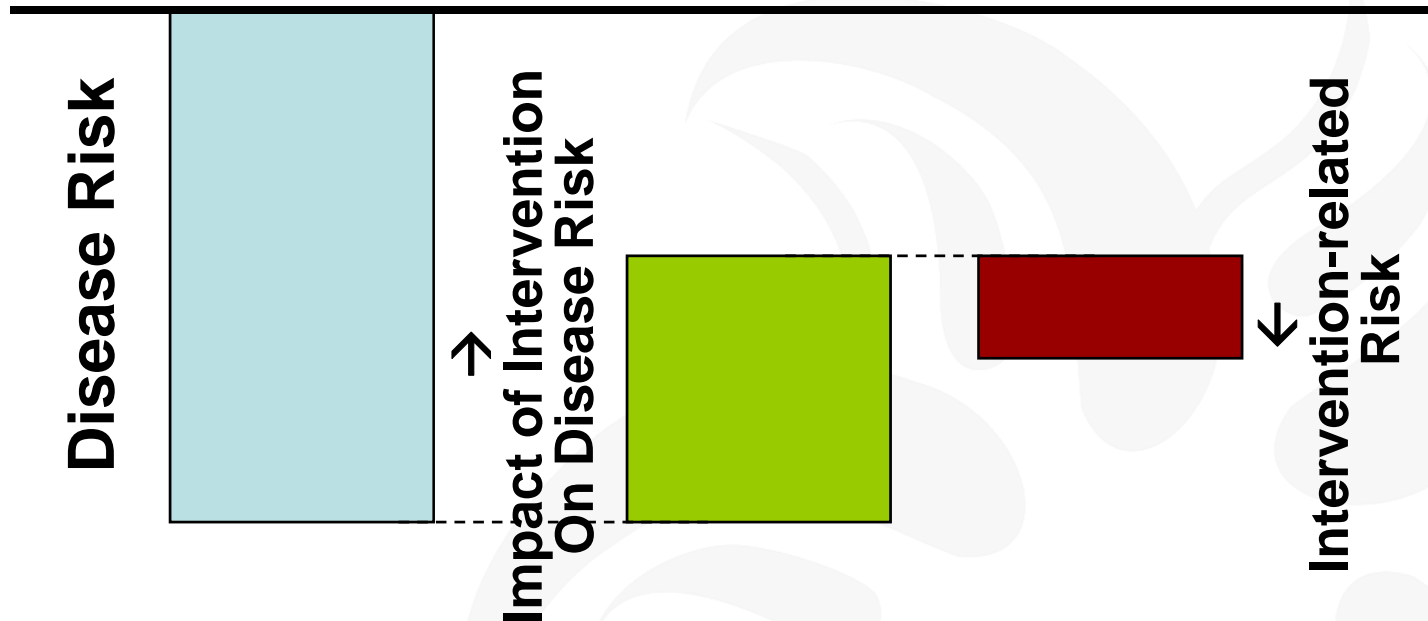
Patient behavior changes

Changing Standards for Policy  
Makers

CNS research has to re-invent  
itself or disappear ...

# A Different View of the Landscape

“Otherwise Healthy Population”

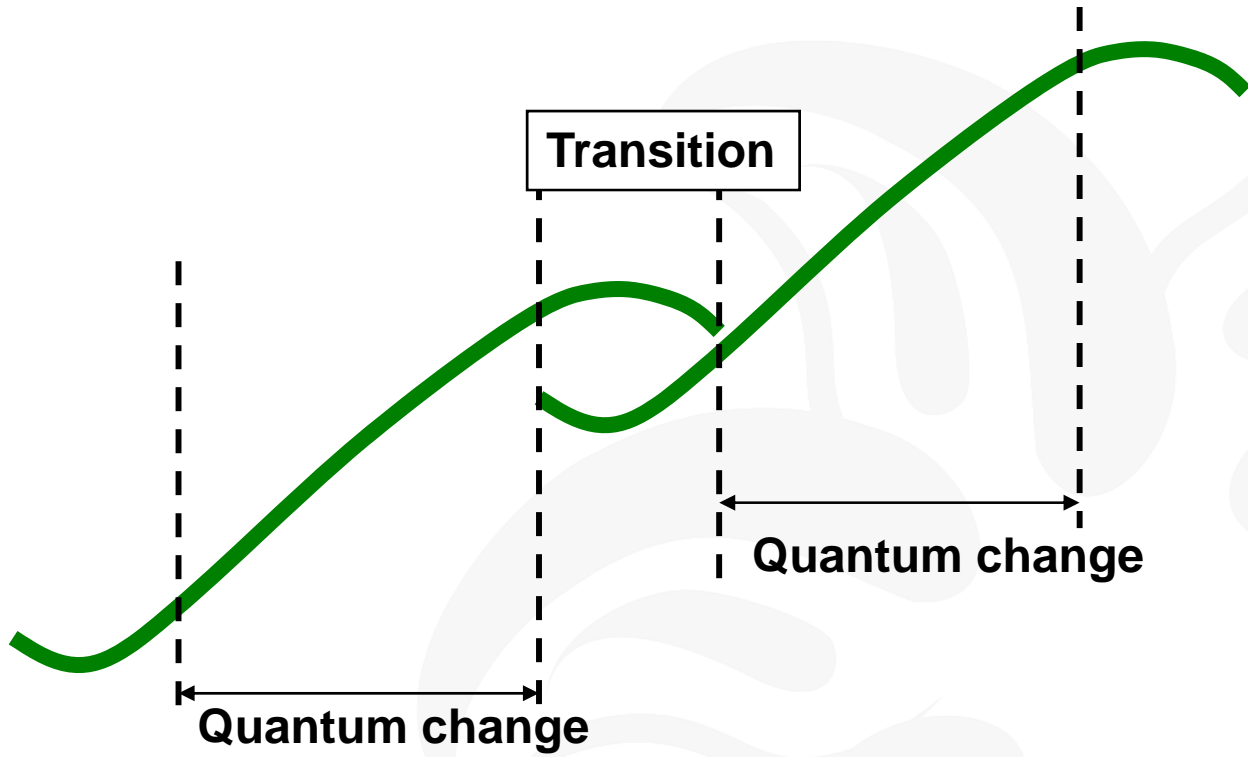


How to quantify  
the impact of an  
intervention  
on the disease?

How does the  
intervention fit in  
the treatment  
algorithm?

What is the value  
for patients, payors  
and physicians

# Looking forward



# ISCTM 09 – Adapting CNS Methodology to Future Needs

- The 09 National Mental Health Research to Policy Forum
- Development of treatments for Bipolar Depression
- Improvement methodology of RCTs for PTSD
- Recent FDA decisions on approval of antipsychotics: a redefinition of risk – benefit assessment
- ISCTM-ASENT joint meeting:
  - Cognition across the CNS spectrum
  - Methodological issues in traumatic brain injury

# ISCTM 09 – Adapting CNS Methodology to Future Needs

- Expand to more patient-centric approaches
  - Functioning or proxies for functioning
- Impact of new interventions on treatment algorithms
  - Move from efficacy to effectiveness approaches
- Personalized medicine in CNS disorders
  - Patient-tailored interventions