

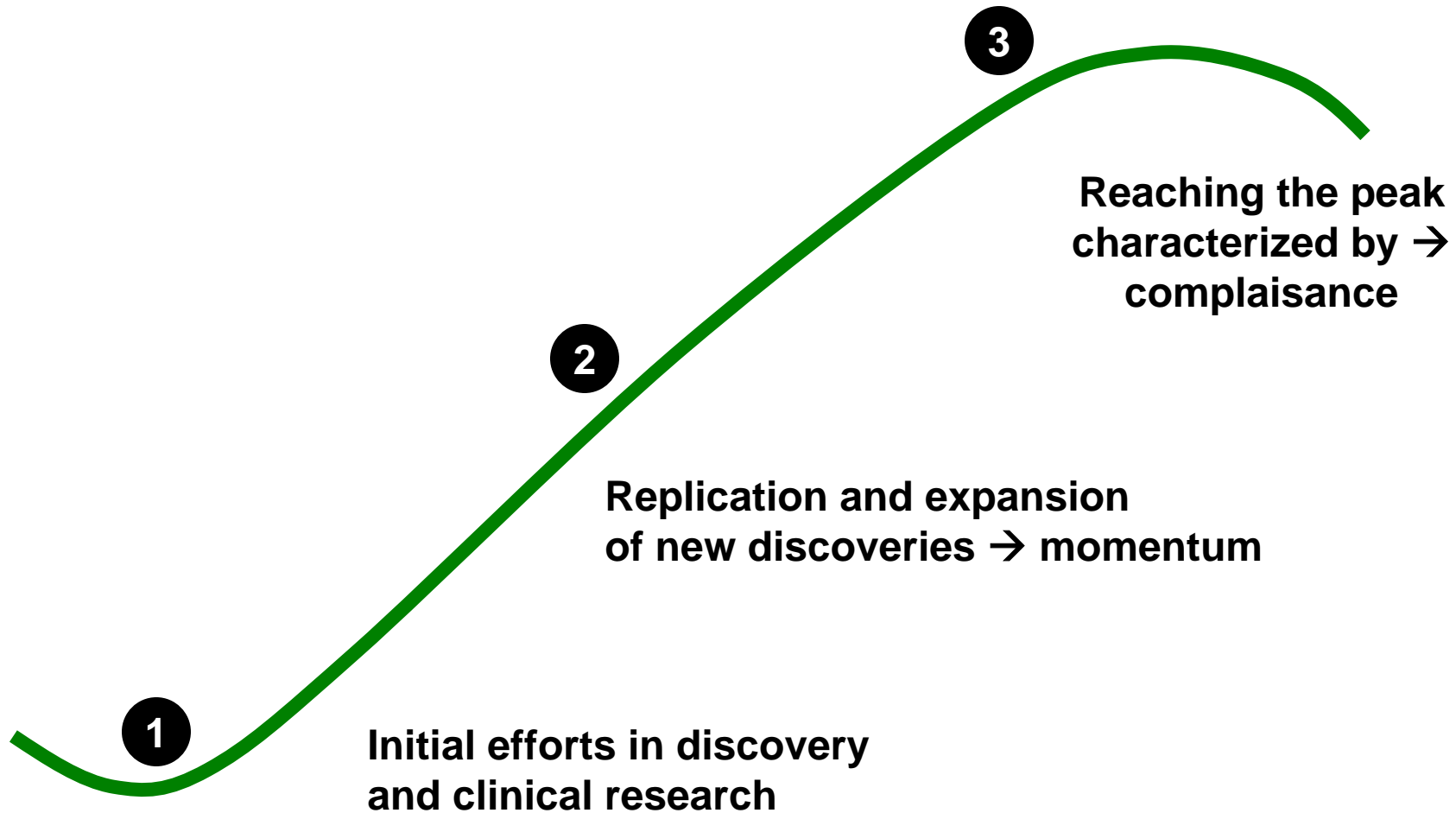
International Society of CNS Clinical Trials and Methodology (ISCTM)

**George Gharabawi/Garibaldi, President ISCTM
Washington DC, February 25, 2008**

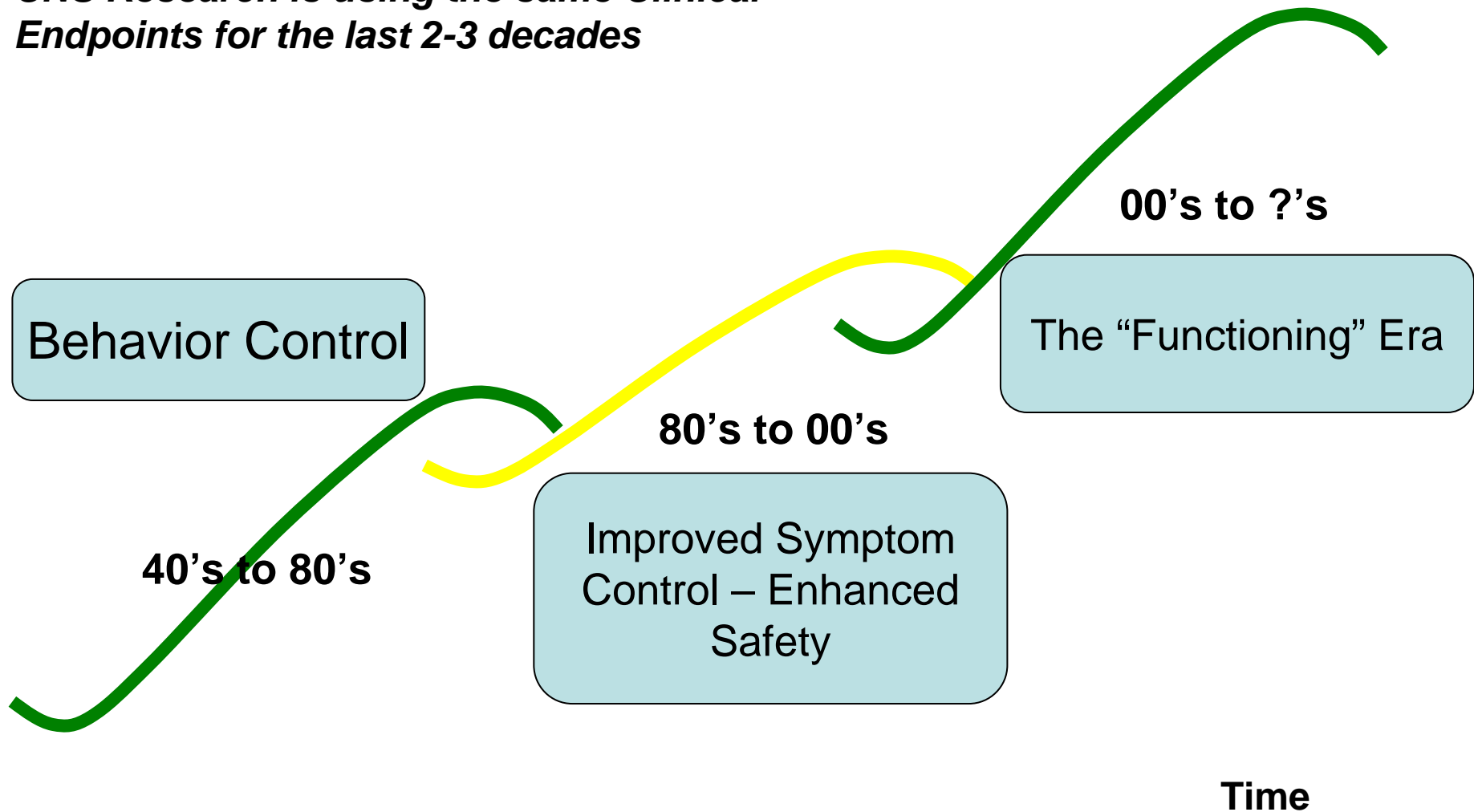
Founded in 2004 as an independent not-for-profit multidisciplinary organization devoted to addressing clinical, regulatory and methodological challenges that arise in the development and clinical use of CNS therapeutic agents

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

Where is CNS on the S-Curve?



*CNS Research is using the same Clinical
Endpoints for the last 2-3 decades*



Paradigm shift in CNS research

- From treatment of overt symptoms to functioning (cognition in schizophrenia, PD, BPD)
- From efficacy to effectiveness
- Early involvement of interested parties (patients, payers)

Enablers of future success

- Diagnostic tools
 - Clinical endpoints for functional outcomes
 - Biomarkers
-

Academia-Industry Collaboration

Large number of collaborations in the USA
(NIMH/Academia and industry)



The Innovative Medicines Initiative (IMI)

3 CNS Topics

- Pain research
- Psychiatric disorders
- Neurodegenerative disorders



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
- 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
-

Past and present collaborations

- NIMH-UCLA (cognition in schizophrenia and negative symptoms)
- Michael J Fox Foundation
- ISCDD

Future collaborations

- ASCENT
-
-

2007-2008 Executive Committee

Georges Gharabawi	President
Ravi Anand	Treasurer
Richard Hartman	Secretary
Larry Alphas	Chair Scientific Program Committee
George Awad	Past President
Munaf Ali	Regulatory Liaison
Ross Baldessarini	Scientific Committee
Larry Ereshefsky	Chair Membership Committee
Ramy Mahmoud	Scientific Committee
Nina Schooler	Scientific Committee
Carlotta McKee	Executive Director

- Loss of 2 society founding members
 - Jack Grebb
 - Dan Blevins

Future Challenges

- Expanding membership and creating broad base
 - Ensuring financial solvency
 - Enhance Scientific rigor and excellence
 - Engage membership in ISCTM activities
 - Increase collaboration and partnership with other relevant societies and organizations
 - Explore avenues for communicating ISCTM contributions
 - Adhere to the independent nature of ISCTM
-
-