

Answering the Call for Change: Lessons Learned and Best Practices - A Funder Perspective

Magali Haas, MD, PhD

CEO & President, Cohen Veterans Bioscience

About Cohen Veterans Bioscience (2016-present)

We are a national, nonpartisan 501(c)(3) research organization dedicated to fast-tracking the development of diagnostic tests and personalized therapeutics for the millions of veterans and civilians who suffer the devastating effects of trauma-related and other brain disorders.

2019 TRAUMA SCORECARD	PTSD	mTBI
# of FDA Approved Diagnostics	0	3*
Qualified Biomarkers	0	1?
Diagnostic Pipeline	?	1+
# of FDA Approved Therapeutics Overall	2	0
# of Therapeutics Approved in Past 17 Years	0	0
Therapeutic Pipeline	>20	>20



A Platform Approach

Our Approach is to **Build Enabling Platforms** with **Strategic Partners**, incentivizing a **Team Science** approach to fast-track solutions.

Reproducibility – Robustness - Rigor



Specific Challenges: Reproducibility

Research findings advance science only if they are significant, reliable and reproducible.



Preclinical – sponsorship of projects to change the paradigm



Joint press release, ECNP and Cohen Veterans Bioscience

World's first prize for "negative" scientific results announced

Embargo until: 00.01 CET (Amsterdam), Wednesday 8th November, 2017

What is believed to be the world's first prize for published "negative" scientific results, the *"ECNP Preclinical Network Data Prize*" has been announced by the ECNP's Preclinical Data Forum. The €10,000 prize, aimed initially at neuroscience research, is to encourage publication of data where the results do not confirm the expected outcome or original hypothesis.

AMP-IT-UP Consortium



Mission is to drive the development of **robust**, **reproducible**, and translational preclinical models of trauma on the brain by focusing on constructs, bridging the translational divide, creating best practice and data standards, and utilizing cutting-edge technologies and computational approaches.



CONFIDENTIAL DO NOT DISTRIBUTE



WE ALL MEET IN THE COMMONS

THE NEXT-GENERATION DIGITAL ECOSYSTEM FOR TRANSLATIONAL RESEARCH

A big data cloud-based platform for computational discovery designed for the brain health community.

SECURE. SCALABLE. SUSTAINABLE.

ENTER THE COMMONS

Working on a Preclinical Data Model leveraging NIH Preclinical CDEs!





Funder's Levers

- RFA process give feedback! Blind the reviewers
- Intramural experts work collaboratively with partner institutions in the conduct of the programs (CVB team has industry-seasoned experts in data science, R&D, diagnostic development, preclinical modeling, etc)
- Ensure that a Statistical Analysis Plan is developed *up front* and executed (provide support when needed)
- Provide the tools and training needed for reproducibility (e.g. the Preclinical Check-list, Biomarker Bake-off results)
- Require real-time data transfer of *all* results (and methods), utilization of CDEs & data standards and require data-sharing through grant agreement mechanisms and enforce by tying to milestone payments
- Ensure funding for data curation/management and open publication fees within grants, and for platform maintenance within organizational budgets
- Support multi-disciplinary consortia efforts that develop and/or disseminate best-in-class methods with academia & industry
- Invest in next-generation technologies and platforms

