

Summit Sentinel

Working for a Victory Over Parkinson's

www.SummitforStemCell.org

Stem Cell Clinics and the FDA: *What happens next?*

In November 2017, the regenerative medicine policy framework was created by the FDA to encourage the creation of regenerative medicine therapies. By doing so the potential that stem cell therapies hold to “treat diseases or conditions for which few treatments exist” was acknowledged. Currently, there is only one stem cell-based treatment *approved by the FDA*, blood-forming stem cells for blood diseases. The new policy provided guidance and clearly indicated the FDA’s intent to “exercise enforcement discretion” regarding the use of unapproved stem cell-based therapies. Recognizing that some of the 1,000 clinic locations around the USA might be conducting promising studies, the FDA announced an “enforcement discretion period” or grace period from November 2017 through December 2020, allowing the opportunity for clinicians to submit an Investigational New Drug (IND) or marketing application. This invitation to submit applied to “products that do not raise potential significant safety concerns.” Because of the pandemic, the grace period was extended to May 31, 2021. Now that the discretion period has ended, it is disappointing to learn that very few clinics took advantage of the opportunity. ***What happens next?***

READ MORE on this subject from Dr. Paul Knoepfler editor of “The Niche: Stem Cell Blog & Resources” Newsletter/Blog.

[READ MORE](#)

Dr. Knoepfler is our featured speaker on Tues., June 29, 2021
CME WEBINAR 5:00-7:00pm PDT
[REGISTER NOW](#)



STEP UP for a
Victory Over Parkinson's
Help **FUND** Summit's **PROGRAMS**
Now through July 6th
[REGISTER TODAY!](#)

By participating in this event YOU can impact approximately 1,000,000 Americans and 10,000,000 worldwide struggling with Parkinson's by helping to fund crucial programs in education, research and patient support that Summit for Stem Cell Foundation provides to help Parkinson's patients. Exercise is critical for PD patients. Join us in solidarity. Raise funds and Raise awareness! STEP UP and HELP!
www.charityfootprints.com/SummitSTEPUP

Our Mission

Summit for Stem Cell Foundation's mission is to support, educate and raise awareness about the development of today's and tomorrow's evidence-based regenerative medical therapies focused on **Parkinson's disease** and other neurodegenerative disorders. It is our goal to empower patients and caregivers with information to elevate their understanding in order to manage their healthcare.

Our Programs

- Research Program
- Education Program
- Patient Support Program

For more info:
www.SummitforStemCell.org

Please!

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WE need your help.

Summit is a 510(c)(3) charitable organization. All donations are tax-exempt. Tax ID #47-4279391

“MOTIVATION comes from working on things we care about”—*Sheryl Sandberg*



UPCOMING EVENTS

CME WEBINAR SCHEDULE

Tues., June 29, 2021

5:00-7:00pm PDT

UNDERSTANDING STEM CELLS:

The Good , The Bad & The Beautiful

Featuring : Paul Knoepfler, PhD

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Tues., July 27, 2021

5:00-7:00pm PDT

THE PATIENT ADVOCATE:

Today & Tomorrow

Featuring:

Benjamin Stecher
(Patient Advocate),
Kevin McCormack (CIRM),
Jeanne Loring, PhD

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MDs, PAs, RNs, and the public
WELCOME!

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SAVE THE DATES

FOR UPCOMING WEBINARS:

Tues., August 24, 2021

Tues., September 28, 2021

Tues., October 26, 2021

All at 5:00-7:00pm PDT

Our WEBSITE is updated regularly to keep you informed on the latest news. We appreciate your interest and patience.

Please DONATE TODAY

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ASPEN NEUROSCIENCE UPDATE:

2021 has been a busy year so far for Aspen Neuroscience. The company is preparing its data package to submit its first therapeutic candidate (autologous stem cells) for Parkinson's as an "IND filing" next year to the FDA! There is a lot of work, and years of research, that go into preparing a submission to FDA for consideration to move into the first human studies. This year, for Aspen this includes finalizing data and studies as part of this package, including a toxicology study and a non-human primate study with Dr. Marina Emborg in Wisconsin to evaluate safety for the surgical procedure.

- The company hired a new CEO, Damien McDevitt, to lead the company during its next stage of growth and development, and brought in new team members to help. Ana Sousa and Angelyn Lowe have joined as SVP of Regulatory and VP of Corporate Affairs, respectively.
- With this new, larger team in place, it is full steam ahead and Aspen will continue to share more updates with Summit throughout the year.
- For more information, sign-up for newsletter and to register as "Clinical Trial Inquiry": www.AspenNeuroscience.com

MEET ALBERTO ESPAY. MD, MSc, FAAN, FANA



Summit for Stem Cell Foundation, having successfully funded, promoted, *and launched* a promising autologous stem cell-based therapy addressing the symptoms of PD, would like to introduce you to Dr. Alberto Espay. Dr. Espay is professor & endowed chair

of the University of Cincinnati James A. & Joan A. Gardner Family Center for Parkinson's disease (PD) & Movement Disorders. Summit is providing funding for Dr. Espay's Cincinnati Cohort Biomarker Program (CCBP). We believe that this study will effectively identify subtypes of PD and, by doing so, will provide the foundation for a REAL cure. *"There will never be a cure for Parkinson's because Parkinson's is a syndrome. There WILL BE A CURE for individuals with Parkinson's – FIRST we need to biologically define and target the subtypes of Parkinson's..."* states Dr. Espay. To learn more about this subject and why Summit has chosen this particular project to support, please visit our website. [MORE INFO](#)

HELP Summit HELP others... our volunteer staff is overwhelmed. Please donate today and help us fund the salary of 1 person so we may better provide more timely information to you and others.

Yes! I want to HELP by DONATING