



Simmaron Research

Scientifically Redefining ME/CFS

Presented to CFSAC, June 20, 2018
by Courtney Miller, Board President

Simmaron Research: Goals

- Redefine ME/CFS through science
 - diagnostic markers
 - scientific characteristics of subsets
 - research that can lead to potential treatments
- Harness the clinical experience of Dr. Peterson and his deep characterization of patients



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Simmaron Accomplishments

- Helped drive a strategic focus on immunological studies
- 15 peer reviewed publications
- Published spinal fluid studies with immunological findings
- Collaborated in publishing subset findings:
 - Short duration v long duration
 - Classical v atypical cases
 - ME with and without Irritable Bowel Syndrome



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NIH Center Grants: Pivotal & Promising



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Proud Collaborator in NIH Centers

- Dr. Lipkin's Center for Solutions to ME/CFS
 - Dr. Peterson is clinical collaborator
 - Deepens Simmaron's 6-year partnership with Columbia Univ.
- Dr. Maureen Hansen's team at Cornell
 - Simmaron will provide samples
 - Satellite collaborations



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Treatments Are Priority #1:
Challenge for all of Us

The Promise of Treatments

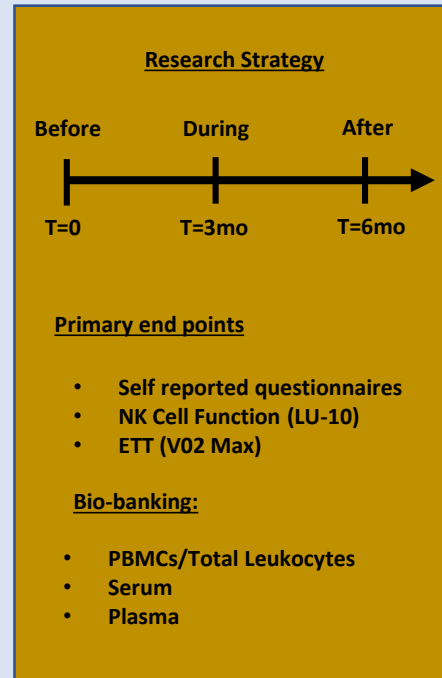
- Treatment is the most pressing unmet need
- Treatment trials are all but non-existent
- How do we change this?
 - Define responders to Ampligen, cidofovir, antivirals, rituximab, etc
 - Train doctors to treat
 - Insurance coverage for patients--would more receive treatment of off label drugs if they could afford it?
 - Would there be more pilot data?
 - Get FDA approval for first ME drug

Simmaron's Treatment Work

- Ampligen Restart study – Cornell collaboration
 - 13 responders who have been off drug for 1 year
 - Other IV treatment comparison
 - Matched by age, gender
 - Antivirals (Cidofovir), amino acids, IVIG, saline and no treatment
 - Measure functionality (common data elements), VO2max (before and after), immune system markers (NK cell and others) every 12 weeks.
 - Lab research on samples collected before, during and after (monthly)
- Ampligen retrospective analysis
 - Massive dataset—in collaboration with CDC (Unger, Lin)
- CFSAC Working Group on Treatment Trials

Intravenous Therapies at Sierra Internal Medicine--are they disease modifying? A prospective analysis

Intervention	IVIG N=30	Antiviral: Cidofovir N=14	Amino Acids N=22	Saline N=50+	★ Ampligen® (Phase III) N=13
Indication	(OFF LABEL) Expensive, hard to get approved	Recurrent Herpes Virus infections	Abnormal AA Panel (CSF/Blood) Intestinal dysbiosis	POTs; Autoimmune?	Fakuda & Canadian Criteria 2018: Prev. Responders
Mechanism	Antibody Replacement & Immune Modulation	Decreasing viral load	Raw materials	Increased Blood Volume	DS-RNA compound,TRL-3 agonist--INFγ



★ 13 pts on holiday since 05/17

Current Studies

- Phase 2 of Columbia spinal fluid studies should be published shortly
- Columbia lymphoma spinal fluid study
- SUNY Albany autoimmunity and family history
- Cornell Seahorse study
- Pilot Data Aggregation
 - TRMP3 SNP allele frequency
 - Mast cell activation cohort analysis
 - Gamma/Delta T-Cell rearrangement status
 - Autoantibodies in ME/CFS patients (muscarinic/cholinergic)--POTS
 - Longitudinal analysis of cytokine status in response to therapy

More information

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