AFIRM as a model for technology-focused federal funding

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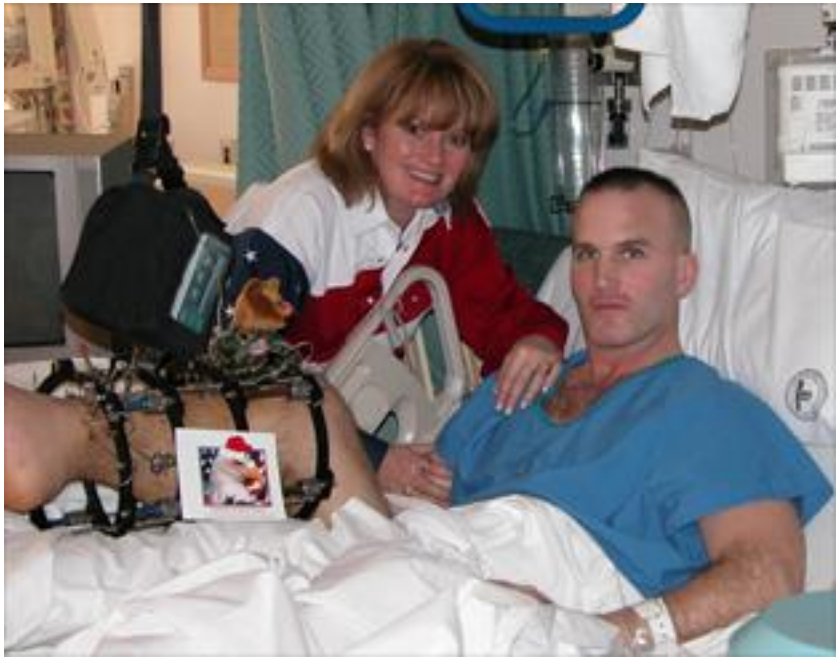
AFIRM: Our Mission



Marine 1st Sgt. Kasal was wounded in Fallujah, 2004.
Courtesy of www.ourmilitary.mil

- To develop a comprehensive program in support of the wounded service member, including
  - Research and development of new therapies and regenerative products
  - Coordination of innovative clinical trials

What is the AFIRM?

- Two consortia working together with the US Army Institute of Surgical Research
  - 230 scientists at 27 Universities
    - 114 senior investigators –30% of which are clinicians
    - 46 graduate students
    - 70 post-docs
- Total 5 yr funding of >$250M
  - $100M US Government funding from:
    - Army, Navy, Air force, VA, and NIH
  - $68M Matching funds from:
    - State governments, and participating universities
  - $109M in pre-existing research projects directly related to the deliverables of the AFIRM from NIH, DARPA, Congressional plus-ups, NSF, philanthropy

Comparison with the NIH model

- NIH or NSF Model
  - Grants or contracts are in the range of $300k per year
    - Ideal for funding basic science up to “proof of concept”
    - Product development or advances toward clinical trials are unattainable at this level of funding
    - Research “piles up” at the proof-of-concept stage
    - The average researcher has nowhere to go after reaching “proof or concept” except to come up with his next great idea and develop another “proof of concept”
    - Distributing small amounts of funding among a large number of “hungry” labs generates more competition than collaboration. Synergy between labs working on the same topic rarely occurs

The AFIRM Model

- Coordinated funding streams lead to development of marketable products and therapies
- Funding decisions are made based on expected commercial impact and warfighter need
- Competing labs are encouraged to collaborate, generating significant synergy

Coordinated funding streams

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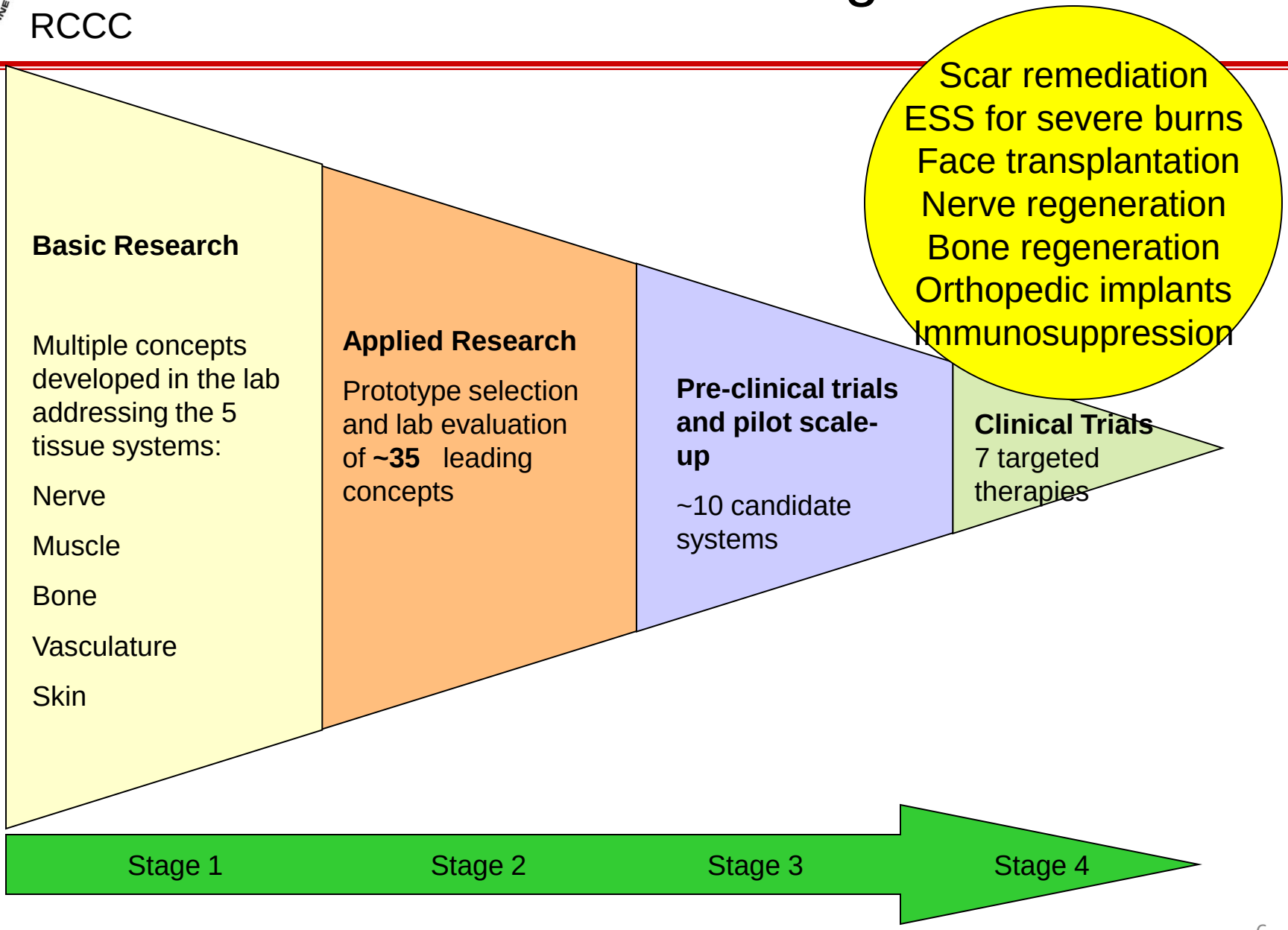

Synergy in a net-centric organization

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- **US Army Institute of Surgical Research**
- **Brooke Army Medical Center**
- **Walter Reed Medical Center**

- **Industry**
  - BonWrx
  - Kensey Nash Corporation
  - Lonza Walkersville
  - Musculoskeletal Implant Foundation
  - Nornal Noble
  - Osteotech
  - Proxy Biomedical
  - Therics
  - Tolera Therapeutics
  - Trident Biomedical

- **Rutgers – Cleveland Clinic Consortium**
  - Rutgers /New Jersey Center for Biomaterials
  - Cleveland Clinic Foundation
  - Carnegie Mellon University
  - Case Western Reserve University
  - Dartmouth Hitchcock Medical Center
  - Massachusetts General Hospital / Harvard Medical School
  - Massachusetts Institute of Technology
  - Mayo Clinic College of Medicine
  - Northwestern University
  - State University of New York at Stony Brook
  - University of Cincinnati
  - University of Medicine and Dentistry of New Jersey
  - University of Utah
  - University of Virginia
  - Vanderbilt University

Major Programs of RCCC

Rutgers - Cleveland Clinic Consortium
Regenerative Medicine Programs

- **Limb Salvage (Nerve and Bone)**
- **Cranio-maxillofacial Reconstruction**
- **Burns and Inflammation Healing without Scarring**
- **Clinical Trials**




Synergy: Clinical Trial Coordination Across about 30 Institutions

- Rutgers-Cleveland Clinic has established a Clinical Trial Core at CWRU (Leader: Stanton Gerson, MD)
  - Assist investigators in clinical trial design
  - Biostatistical support
  - Protocol writing and guidance
  - Regulatory assistance (IND, IDE preparation)
  - Protocol implementation assistance
- Clinical trial database access and support “OnCore®”
  - Web-based access for coordination of multicenter trials
  - Patient accrual tracking, protocol, subject calendar, financial management, database quality assurance
  - Regulatory management: tracking of adverse events and reporting to IRB, FDA, HRPO
  - Data management and reporting: data output to Excel or SAS
  - FDA 21 CFR part 11 compliant

Seven projects have advanced to clinical trials or regulatory submission to the FDA within the first 24 months of AFIRM funding

Trial 1: Composite Tissue Allograft Transplantation for Face

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- RCCC has focused on patients with massive facial tissue loss
- The team led by Maria Siemionow, MD Cleveland Clinic Foundation performed the first “face transplant” in the USA
- Recruiting patients for clinical trial; expect additional transplant within the next 6 months. Funding ($2 mm) for a total of additional 2 patients
- Regulatory: IRB and DoD contingent approval. Screening patients
- Major advantage: Optimal functional and cosmetic restoration
- Major challenge: Immunosuppression therapy

Other advanced AFIRM technologies

- Trial 2: Advanced Tolerance Induction as Part of CTA
- Trial 3: Autologous Engineered Skin Substitute for Severe Burns
- Trial 4: Adipose Fat Transfer for Scar Remediation
- Trial 5 : Sural Nerve Repair as a “first-in-man” Test
- Trial 6: “510(k)” Application for a degradable bone pin as a first step to commercialization of bone regeneration scaffolds
- Trial 7: Assistance in commercialization of a new bone void filler

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Key points

- Coordinated funding for centers, labs, or institutes has more impact on innovation and technology development than distributing small grants to lots of labs
- Funding across the technology development spectrum is needed to propel ideas from concepts to products
- The “AFIRM” can be a new model for major funding initiatives that have well defined technology goals