

## TRAUMA CLINICAL TRIALS NETWORK

### Background

Trauma is a major cause of death and disability in the United States and the second most expensive health care problem after cardiovascular disease:

- Trauma is the leading cause of death of all Americans ages 1 through 44.
- Each year trauma accounts for **41 million** emergency department visits and **2.3 million** hospital admissions across the nation.
- Over 180,000 Americans die from trauma each year.
- Trauma injury accounts for 30% of all life years lost in the U.S., and because trauma affects all ages including the young, the impact on life years lost is equal to the life years lost from cancer, heart disease and HIV combined.
- The economic burden of trauma amounts to over \$400 billion a year, including both health care costs and lost productivity.

Yet despite this prevalence, improvement in trauma care has lagged behind diseases such as cardiovascular disease, cancer and HIV/AIDS. Management of trauma patients has been primarily guided by prior physician experience and preferences and not by robust research or evidence-based guidelines. Clinical trauma investigators generally pursue research topics of personal interest, without reference to priorities or critical research gaps.

### Proposed Solution—Clinical Trials Network

Recent successful models of collaboration resulting in funded national treatment and research programs include those related to Traumatic Brain Injury (TBI), Post-Traumatic Stress Disorder (PTSD), and the Armed Forces Institute of Regenerative Medicine (AFIRM). Key federal departments and the White House worked together to take steps to meet the demand for research and treatment in these areas.

Advancing trauma treatment requires coordination of priorities that address critical research gaps, i.e., a national trauma research agenda. The research agenda will be addressed by multiple academic and military trauma centers. Individual trauma centers cannot enroll enough patients at one location to conduct a study with significant statistical power; therefore a coordinated group of trauma centers with combined patient populations is needed. Benefits of a network include:

- Creation and pursuance of the national trauma agenda and closing of prioritized research gaps
- Known track records of investigators
- Validation of proven findings from different regions and populations, leading to wider acceptance of clinical outcomes

**Concept:** The US government would create a combined trauma task force of federal departments and agencies focused on advancing trauma research with these general parameters:

- The task force will define research guidelines and priorities.

- A Clinical Trials Network of up to fifty (50) trauma centers will be formed.
- A coordinating center will manage the studies and be responsible for the peer-review process to review proposals and award studies; manage contracts; and execute monitoring and compliance activities, under the direction of the trauma task force.

### **Conclusion**

The estimated cost to establish a national trauma clinical trials network and initiate trauma research on a meaningful scale is roughly \$30 million. Well-organized and funded trauma research will produce the same impact that funding of heart disease and cancer have achieved. Even a 5% reduction in trauma deaths, injuries and the economic burden would save 9,000 lives, prevent 1.5 million injuries, and save the US \$35 billion every year.