

CLINICAL TRIAL COMMUNICATIONS

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Since the original thrombolytic mega-study GISSI (Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardico) in 1987, MCS has been creating and executing innovative public relations programs that accelerate trial enrollment, increase product awareness and strengthen relationships with investigators and their institutions. Our patient recruitment initiatives support studies in a variety of therapeutic areas and adhere to strict regulatory guidelines and IRB requirements, while our media campaigns supporting trial milestones and results help introduce investigational therapies to key audiences.

Key Clinical Trials:

- ASSENT 2, 3, 3Plus & 4PCI: Assessment of the Safety and Efficacy of a New Thrombolytic
- BCIRG: Breast Cancer International Research Group
- BOND: Bowel Oncology with Cetuximab Antibody
- COOL Trials: Cardiovascular thrombolytic to Open Occluded Lines Trials
- EPHEBUS: Eplerenone Post-AMI Heart Failure Efficacy and Survival Study
- ESSENCE: Efficacy and Safety of Subcutaneous Enoxaparin in Non-Q Wave Coronary Events
- GISSI: Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardico
- GUSTO: Global Utilization of Streptokinase and T-PA in Coronary Occluded Arteries
- IMPACT: International Multicenter Prospective Angioedema C1 Inhibitor Trial
- SYNERGY: Superior Yield of the New Strategy of Enoxaparin, Revascularization & GII coprotein IIb/ IIIa Inhibitors
- TIMI Trials: Thrombolysis In Myocardial Infarction Trials

Creativity, Service and Results:

- In collaboration with Aventis Pharmaceuticals, the Breast Cancer International Research Group (BCIRG) and a number of participating institutions, MCS helped announce the start of and drive patient enrollment in the two largest global clinical trials for post-surgery use of chemotherapy and a biological modifier in the treatment of early stage breast cancer. National and local market media relations created awareness and accelerated patient recruitment, supporting such participating study centers as the University of Texas MD Anderson Cancer Center, Massachusetts General Hospital, Temple University Hospital and Montefiore Medical Center.
- For the international, multi-center clinical trial known as ESSENCE, MCS supported numerous trial milestones and results, including publication of study results in the *New England Journal of Medicine*. As a result of this study, the low-molecular-weight heparin Lovenox® (enoxaparin sodium) Injection went on to become the first prescription drug approved by the FDA for the acute coronary syndromes unstable angina and non-ST-elevation myocardial infarction (NSTEMI). Outreach resulted in stories in more than 200 consumer newspapers, broadcast television programs and trade publications reaching a combined audience reach of more than 21 million.
- To support CSL Behring's C1-inhibitor for the treatment of hereditary angioedema (HAE), MCS developed a variety of pre-approval campaigns, including grassroots initiatives to increase patient enrollment in the company's pivotal I.M.P.A.C.T. trials. In a very competitive race to be the first HAE treatment, our campaigns helped to build product anticipation and raise awareness by highlighting key study milestones and results with influential trade media outlets, including *Reuters*, *HemOnc Today* and *Scrip World Pharmaceutical News*.