



## **CRF Health is First to Gain FDA registration, and 21CFR 820 Recognition, of their TrialMax<sup>®</sup> ePRO System as Medical Device**

Plymouth Meeting, PA – September 27, 2011: In accordance with the new FDA regulation, set in April this year, CRF Health's TrialMax<sup>®</sup> has become the first ePRO system to complete its Medical Device registration, a regulation that concerns medical device data systems (MDDS) that collect information from apparatus such as spirometers and glucometers.

TrialMax<sup>®</sup> is categorized as a Class 1 MDDS under regulation 21CFR 880.6310 (code OUG). And because it uses alarms to remind subjects when to take their study medication, it's also classified as a 'medication reminder' under regulation 21CFR 890.5050 (code NXQ). This makes TrialMax<sup>®</sup> exempt from pre-market review but still subject to medical device 21CFR 820 quality standards, a practice to which CRF Health is fully compliant.

Rachael King, CEO explains, "CRF Health improves data collection by removing the barriers between intimate patient experiences and the technology designed to capture them. Our ability to collect data directly from medical devices, reinforces this philosophy, and our belief that the best way to get the cleanest, highest quality PRO data is by getting closer to the patients than anyone else."

"We strive to make your ePRO experience a positive one," added Greg Gogates, VP Quality Management and Regulatory Affairs. "Our timely response to the new FDA regulation is just another way in which we ensure your clinical study will run as smoothly as possible. Working with us means your clinical trials won't be impeded by new industry requirements," he said. "And, as always, our dedicated project managers will guide you through your study every step of the way, minimizing the risk of delays and maximizing the chance of delivering your study on time."

### **About CRF Health**

CRF Health is a global leader in ePRO (electronic patient reported outcomes) solutions for the life sciences industry. Through innovative technology, a thorough understanding of drug development, and mobile computing, CRF Health is driving the change to higher quality outcomes and more efficient paper-free clinical trials.

CRF Health's ePRO technology has been used in more than 70 countries, on six continents and 68 regional languages, including several regional Indian dialects. CRF Health consistently demonstrates the industry's highest patient compliance rates, while delivering unrivaled data accuracy and unmatched patient and site acceptance.

Since its founding in 2000, CRF Health continues to provide true global ePRO delivery and service. Headquartered in the US, CRF Health operates its R&D center of excellence in Helsinki, Finland and has offices around the world.

For more information, please visit [www.crfhealth.com](http://www.crfhealth.com).

#### **Media Contact**

Heather Bilinski, Marketing Manager

CRF Health

4000 Chemical Road, Suite 400

Plymouth Meeting, PA 19462

Phone: +1 267.498.2349 | Fax: +1 215.565.0001

[heather.bilinski@crfhealth.com](mailto:heather.bilinski@crfhealth.com)