Abbott Response to World Health Organization
International Clinical Trials Registry Platform (ICTRP)
Request for Open Comments on Disclosure Timing
March 31, 2006

Abbott provides the following response to the WHO ICTRP invitation to comment on how to balance the protection of competitive advantage with the need for transparency in trial registration via the WHO ICTRP website (http://www.who.int/ictrp/comments4/en/index.html). In addition, Abbott provides comments on select topics associated with the registry platform that must be addressed in order to ensure a successful project.

Competitive Advantage vs. the Need for Transparency (Disclosure Timing)
Abbott agrees with the Registry Platform that all 20 items in the Registration Data Set should be fully disclosed at the time of registration for the overwhelming majority of hypothesis-testing (non-exploratory) clinical trials. However, Abbott foresees that there may be infrequent instances where full disclosure of one or more of select data items (e.g. 10, 13, 17, 19 and 20; official scientific title of the study, interventions, primary outcome, key secondary outcomes, and target sample size; respectively) could place a sponsor at a competitive disadvantage as was recognized at the WHO Technical Consultation on Clinical Research Standards Meeting on 25-27 April 2005. Therefore, it is imperative that sponsors maintain their rights to delay disclosure of the commercially sensitive information.

Abbott foresees that disclosure of select data elements should be delayed rarely and that the length of the delay should be brief. Disclosures should occur as soon as the information is no longer commercially sensitive and when intellectual property protections are in place. Disclosure should generally occur before product approval, but at the latest, at product approval.

Because disclosure should be delayed infrequently, it is not apparent that a special mechanism needs to be developed to handle these instances. The development of a specialized process may require more time and effort than the value returned to stakeholders.

Scope of Trials to be Registered
Registering ALL trials, including early phase trials, is not in the best interests of the stakeholder community. Phase 1 trials are largely focused on the safety of new compounds in humans; are designed as dose toleration, ADME studies in healthy volunteers; and are not interventional, as they do not evaluate health outcomes. These trials do not result in information that can inform clinical practice. Therefore, we recommend that the WHO ICTRP register only those trials that inform health and healthcare practice and exclude exploratory trials as agreed upon at the April 2005 WHO Technical Committee meeting.

Unique Identifier
Abbott notes that the WHO process to assign the UTRN (Universal Trial Reference Number) is similar to protocol identification systems in place at universities, pharmaceutical companies, and trial registries, also aimed at avoiding duplication. It is not evident how the tagging of studies with a WHO-assigned identifier adds value beyond what can be provided through the Primary Registers. We suggest that WHO focus its efforts on running duplication checks of the content of select data fields rather than adding an UTRN.

1 As defined in the January 6, 2005 PhRMA Principles for Clinical Trial Registries