

## **Challenges in Performing High Quality Clinical Research**

It has long been recognized that a rigorous clinical research program improves the quality of patient care, increases the opportunities for new types of care and helps to recruit the best and brightest physicians and staff. Watson Clinic Center for Research, founded in 1986, accomplishes those objectives.



The Center is a tool to permit researchers from all branches of the Watson Clinic to become involved in very high quality, intellectually rewarding clinical research. The Center has completed over 400 protocols involving more than 5,000 patients and is actively running more than 80 research protocols. Eventually, the Center hopes to involve all divisions of Watson Clinic.

Clinical research in the United States is divided into four types. Phase I trials are performed with human volunteers. It requires a very extensive informed consent and evaluation of patients before initial exposure to a drug or device. The Center for Research does not perform this type of study. These are usually relegated to large research programs that have extensive volunteer networks.

Phase II trials are early trials of devices or drugs where a small number of patients will be enrolled in a carefully supervised setting with strict follow-up. Watson Clinic Center for Research performs these trials, which are very labor intensive and require extensive regulatory involvement. Usually, the studies are limited to less than 150 patients and occur in three or four specialized centers.

Phase III trials are much larger trials, usually encompassing several hundred to several thousand patients. These trials are randomized between the new agent and an existing treatment. The trials collect safety and efficacy data on the investigational agent and are considered the pivotal trials for the FDA to approve a new device or drug in the United States. Most trials performed at Watson Clinic Center for Research are of this type.

Phase IV trials are usually performed to further expand on the findings in the Phase III trials. Sometimes the studies are performed after the drug or device has been approved by the FDA. The Center for Research spends a great deal of time working with the local and national institutional review boards, sponsors and the FDA to assure that studies are appropriately developed and correctly performed. Deviations from protocols, adverse events and specific endpoint outcomes need to be collected in a careful fashion so that when the trial is complete the data will be analyzable.

The Center for Research has been involved not only in multi-center national trials but also in single-center trials. An example of which is seen in the recent trial of grapefruit interaction with atorvastatin. This trial was developed at Watson Clinic Center for Research and completed involving only patients from the Watson Clinic. Other trials have been performed involving two or three centers, and some trials have involved as many as 500 centers.

Future plans for the Center for Research include the development of outreach efforts to offices and other medical facilities, further development of in-house statistical capabilities and continued development of information technology support.

The environment in which clinical research is performed has evolved to the point that specialized personnel are required to successfully perform clinical research trials. As Chairman of Research, I have been fortunate to work with a strong group of research personnel that have backgrounds that include acute care as well as laboratory skills. These people are the backbone of our clinical research group and have permitted the Watson Clinic Center for Research to be recognized nationally for performing high quality, complex research trials.