'Clinical trials are perfectly aligned with our mission'

Robert Golden, dean of the UW-Madison School of Medicine and Public Health, responds to criticism about how the university handles clinical trials. The Q&A was edited for continuity.

Why did you commission the Westrick Report?

Dean Robert Golden: Based on feedback from industry and our faculty, and confirmed by our own observations, we realized that there were inefficiencies and room for improvement in our underlying infrastructure for clinical trials. This is not unique to UW-Madison. If you've done research into the Alliance for Clinical Research Excellence and Safety (ACRES), you are already aware of concerns regarding inherent inefficiencies in the current clinical trial framework in the U.S. and abroad.

Following a series of "listening sessions" with partners in industry, the vice chancellor for research and graduate education [Norman Drinkwater] and I felt that an important initial step forward would be to engage an outside expert with leadership experience in the conduct of clinical trials.

With support from Chancellor [Rebecca] Blank, the School of Medicine and Public Health (SMPH) joined together with our academic health system, UW Health, in inviting Dr. Mary Westrick to complete an assessment. Dr. Westrick was beginning to work with the emerging ACRES in developing the standards for a new global accreditation system for clinical trials.

What jumps out at as the most critical take-away messages from the Westrick Report?

One critical message is: We must continue to enhance our existing quality-improvement system for ensuring consistent effectiveness and timeliness in approving and completing clinical trials. Another message involves the opportunity to expand communications with our faculty and staff, as well as with our community of potential research participants, regarding the importance of clinical trials, and to recognize and support them.

Why was there such a delay between the Feb. 1, 2018 draft and the Sept. 24, 2018 final report?

The February version was an interim draft that was reviewed while Dr. Westrick continued to gather input and data from our internal stakeholders and external partners. Also, the ACRES standards for clinical research were released for public review during this period, which provided an opportunity to refine some recommendations that would take into account those standards.

Did the focus or content change much?
No, although the additional feedback from stakeholders, consideration of the newly available ACRES accreditation standards (which were published after the February draft), and updates in certain areas are reflected in the final report.

What are the implications for UW-Madison of nationwide accreditation standards being established for clinical research sites?

Please note that the standards are global/international in scope, rather than national. Accreditation based on these standards will make it easier for multiple accredited sites to form clinical trial networks on short notice, and will demonstrate our current and continuing commitment to excellence, performance and safety in our clinical trials research.

Do you agree with the Westrick recommendations on the way UW should proceed?
I agree with many of the recommendations in the report. Others are not feasible, or even desirable. The new chief clinical research officer will be tasked with analyzing the current status of our clinical trials program and with developing a plan for implementing the ACRES accreditation standards referenced in Dr. Westrick's report.

How is the UW School of Medicine and Public Health following up on the recommendations?
As an initial step, we created a new position and are now recruiting for a director of clinical trials development. This individual will possess relevant experience in industry and a solid record of achievement in regulatory matters, quality systems, and operational excellence. SMPH staff has also become engaged in the work of ACRES by participating in the testing of the new accreditation standards at other institutions.

Is there a timetable for action?
We hope to have the new director of clinical trials development on board by late Spring/early Summer. We will then develop a timetable for review and improvement of our processes and begin work on the implementation of the ACRES global accreditation standards for clinical trials.

Is there a connection between Rock Mackie being named UW Health's chief innovation officer and the issues that Mary Westrick investigated for the Med School?
No. When Dr. Alan Kaplan became the UW Health CEO, he launched a strategic planning process. The resulting roadmap included research and innovation as a major focus for the health system. The implementation of that pillar of the strategic plan includes the creation of an "Innovation and Discovery" program, which Rock will lead in

his new capacity as UW Health's chief innovation officer. It will focus on advancing the development of new ideas generated by UW Health. Mary Westrick was brought in to help the university and UW Health advance our ability to perform clinical trials with external partners in industry, as well as for faculty investigators.

Is the UW positioned to gain accreditation? Or is significant work needed to reach that point?
The voluntary accreditation standards that are being developed by ACRES will be available for adoption across the nation and globally in the next 12 to 18 months. Like many institutions, UW-Madison and UW Health will need to focus time, attention and resources to fulfill the new requirements and metrics.

Why are the ACRES standards important?
The new accreditation standards are the result of decades-long discussions involving both industry and academia, with the realization that ensuring consistency and high performance at research sites across the nation and throughout the world is vitally important. Dr. Westrick's recommendations anticipated many of the accreditation standards. Specific decisions about the best way to proceed will be the major component of the portfolio of the new director of clinical trials development.

Dr. Drinkwater says the Westrick Report fails to substantiate its claims and proposals. He states that the university wants to know about situations in which a research project was unjustifiably delayed or disapproved. However, he says, the report provides no examples of such situations. How do you respond to his complaint that the report does not substantiate its findings?
Dr. Drinkwater did not state, as the question implies, that the report fails to substantiate all of its claims and proposals. More specifically (as per your question below), he indicated that the report failed to substantiate with factual rationale the suggestion that UW Hospital would be better suited for controlling the clinical research infrastructure.

Dr. Drinkwater also says the report is simply in error, for example, on finding that the UW's Institutional Review Board takes an excessively long time to approve clinical trial protocols submitted by campus researchers.
IRB turnaround time will vary depending on how it is measured. Applying a widely used methodology for measurement, UW-Madison's IRB turnaround time is consistent with national norms*.

Do you agree with the Westrick recommendation that oversight of clinical trials be shifted to UW Hospital from the vice chancellor for research and graduate education? If

yes, why? Note that Dr. Drinkwater says the Westrick Report provides no factual rationale for moving that task from his office.
No. UW Hospital is a critical partner of UW-Madison in the conduct of clinical trials by university researchers. However, as Dr. Drinkwater noted, it is statutorily prohibited from managing research activities conducted by UW-Madison investigators, and it does not have the considerable infrastructure in place that UW-Madison has to oversee clinical trials.

The administrative home for the Institutional Review Board, which is one component in the review process for proposed clinical trials, has now been shifted from the School of Medicine and Public Health to the office of the Vice Chancellor for Research and Graduate Education. We (the School of Medicine and Public Health) were involved in the planning of this move and support it.

Finally, why is this stuff important?
The School of Medicine and Public Health and UW Health share a mission statement: “Advancing health, without compromise, through **service, scholarship, science**, and **social responsibility**. *[Golden's emphasis.]* Providing an outstanding environment and infrastructure that offers our patients the opportunity to participate in clinical studies is perfectly aligned with our mission.

* Westrick in her report and in an interview pointed out that a survey of campus researchers documented substantial unhappiness with the IRB process, including lengthy delays in the "pre-review" stage of protocol assessment.