

UW-Madison Announces Clinical Trials Institute— Alliance with Site Accreditation & Standards Institute (SASI)



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A major academic medical center in the Midwest has established a centralized hub for the development of more collaborative, streamlined, effective and efficient processes in the administration and operation of clinical trials at UW-Madison and UW-Health. The new Clinical Trials Institute represents the coming together of UW Health and the UW School of Medicine and Public Health to advance health care innovations via clinical trials at UW-Madison. Led by [Betsy Nugent](#), who has participated in past TrialSite interviews, the group will seek to bolster consistency, quality and safety not to mention optimized resource allocation as UW-Madison ramps up its competitive position in the academic medical research ecosystem. This initiative isn't done in a vacuum. UW-Madison reflected on areas for research improvement which led to a partnership with the novel, disruptive [Site Accreditation & Standards Institute \(SASI\)](#), the first comprehensive trial site accreditation worldwide. UW-Madison seeks to kick up several notches its ability to

conduct, scale up and drive both academic and industry-initiated clinical trials.

TrialSite reported on internal audits done a few years ago at UW-Madison signifying the need to regroup, evaluate and improve the research enterprise, for improvements to quality, patient safety and engagement and competitive performance.

UW-Madison brought on board Betsy Nugent to lead that research enterprise in August 2019, as reported by *TrialSite*. Later that year, Nugent did a podcast with *TrialSite*, discussing how to create foundations for a dynamic clinical research program.

Betsy Nugent, MSPH—the Catalyst



SASI Accreditation Comes out of Stealth Mode

Part of that initiative is with a novel, disruptive trial site accreditation group called the Site Accreditation and Standards Institute, (SASI), as *TrialSite* has reported represents a spinoff of the [Alliance for Clinical Research Excellence & Safety \(ACRES\)](#), a visionary nonprofit group founded by Dr. [Greg Koski](#).

TrialSite's founder, [Daniel O'Connor](#) and *TrialSite Inc.* has collaborated with ACRES early on during the development of the SASI trial site accreditation standard, collaborating with not only Dr. Greg Koski but also quality guru [Dr. Larry Kennedy](#). O'Connor shared, "SASI, under the leadership of Larry Kennedy, is at the forefront of transforming the trial site sector from a fragmented group of mom-and-pop sites to a scalable, sustainable industry dedicated to not only bolstering patient safety and quality but importantly, also ensuring performance."

SASI is working with the recently announced UW-Madison Clinical Trials Institute to earn the novel, pathbreaking accreditation. According to [Dr. Nasia Safdar](#), research director, UW Clinical Trials Institute, "The formation of the institute will allow us to better support UW's clinical research community and help advance innovation and discovery in the prevention, detection and treatment of a range of disease."

What's the Clinical Trials Institute's focus?

Among other things, the prestigious group reports, "new industry partnerships," meaning UW-Madison will extend and enhance its biotech, pharmaceutical and medical diagnostic and device alliances moving forward all in the bid to advance life-saving and enhancing medicines still in early clinical development.

Also, the group plans on improving the support of clinical trials operations throughout UW Health and the UW

School of Medicine and public health, reports Betsy Nugent.

Importantly, as academic medical centers become points of care for cell and gene therapies, newfound clout, leverage and responsibility will become a reality along with the advancing march of industry research into the care clinic.

Academic medical centers must prepare for the clinical research as a care option movement, inevitable and advancing at unprecedented speed.

Dr. Greg Koski—the visionary



On SASI, Daniel O'Connor shared, "It's a visionary movement started by Dr. Koski and operationalized by Larry Kennedy, probably the most prolific quality expert in the country when it comes to the intersection of business, science and trial sites. The demand for this accreditation will surge as the program comes out of stealth mode."

Larry Kennedy, Ph.D.—bringing SASI to market



About SASI

The Site Accreditation and Standards Institute, Inc. (SASI) is a fully independent Delaware nonprofit corporation operating as a "fee for service" (IRS 509 (a) (2)) organization. The nonprofit's singular mission is to continue to update the SASI-QMS:2020-1 Standard for the Quality Management of Clinical Research Sites and to deploy and operate a system of Accreditation with a global span. The brainchild of Dr. Greg Koski, the founder of ACRES, the group under the leadership of [Dr. Briggs Morrison](#) and Larry Kennedy has accelerated the operationalization of the SASI standard in a range of early adopters including UW-Madison. The SASI team includes a core group of top clinical research experts representing industry, academic research and government. The SASI standard has evolved based on the hard work of these expert volunteers and early adopters ranging from major academic centers such as UW-Madison to commercial trial sites seeking competitive advantage.

Call to Action: Learn more about [SASI here](#). Check out uwclinicaltrials.org to learn more about the UW-Madison Clinical Trials Institute and studies at UW-Madison.

References

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