

Confidential

Gibbs Health Institute & the Guardian Research Network

An economic multiplier democratizing clinical trials & revolutionizing drug development

Executive summary

The Gibbs Cancer Center & Research Institute has created the non-profit **Gibbs Health Institute (GHI)** that will lead the development of a cutting-edge, personalized medicine initiative that will have a dramatic impact on healthcare in South Carolina and nationwide. The initiative will (1) “**democratize**” clinical trial access for all patients, allowing trial access to individuals who previously could not afford to travel to tertiary medical centers, and will (2) “**revolutionize**” the drug development process by making trials available to hundreds of thousands of new patients, reducing the time and cost of trials thereby increasing the number of drugs that can be tested.

Currently, only 3% of available patients participate in clinical trials, and less than 10% of those are minority populations. Isn't it ironic that more than 1000 new and promising cancer drugs are waiting to be tested yet there are hundreds of thousands of eligible patients who will never get access to the most promising drugs? Those underserved patients are typically located in local communities where, nationwide, >80% of cancer patients are actually treated. Unfortunately, the patients most disproportionately affected are minority, impoverished, rural, and elderly populations, who generally do not have the means to travel significant distances, particularly during the most challenging phases of their lives. Moreover, the disruptive and often emotional effects on families impacted by cancer who are forced to travel can be overwhelming.

The GHI will oversee a nationwide network of hundreds community-based hospitals and their physicians. This network is called the **Guardian Research Network (GRN)**. Thus, the best trials will be brought to patients, instead of the current practice of forcing patients to travel to clinical trials, usually out-of- town *and* out-of-network. The core engine for the GRN will be a next-gen **sophisticated data warehouse** that connects hospitals nationwide. Network partners will for the first time share and combine **real-time** electronic medical record (EMR) data in a secure fashion from hundreds of hospitals brought together in a single, searchable data warehouse. This will eliminate the time consuming manual and expensive processes currently used to execute Pharma trials. **In the GRN, all patients diagnosed with cancer will have next-generation DNA sequencing (complete DNA sequencing of ~600 genes).** By using this new approach, the GHI will dramatically shorten the time it takes to identify the right subpopulation of patients to complete a trial. GRN “turbo-trials” will tailor the drug trials to the perfect match patients and thus may take only 50% of the time to complete versus conventional trials.



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This time savings coupled with smaller trial size will reduce costs and will attract Big Pharma to South Carolina to bring their best drug trials to the community. The GRN will provide, for the first time, cutting edge trials to community hospitals and their local patients.

Changes in medicine are usually geological, occurring over several decades or more. We believe the GRN is a novel concept that could impact both the way medicine is practiced and delivered and the way drugs are developed within 3-5 years. The GRN will impact hundreds of thousands of patients and will establish a paradigm shift in the drug development industry.

To date, the Gibbs Cancer Center & Research Institute has invested ~\$8M to-date in the GHI/GRN and has created a working prototype data warehouse. Over the next three years, out-of state “ partner” hospital systems will contribute more than \$ 25 million into the South Carolina economy. The GHI/GRN is moving towards a self-sustaining business model supported by both participating hospitals and Pharma to ultimately create a “disruptive innovation” in healthcare and drug development. The GHI will initially create ~100 high paying jobs over the course of the next 5 years, but has the potential of creating many more jobs as the business model evolves towards a contract research organization. In addition, due to the need to develop massive throughput DNA sequencing, the GHI has the potential not only to attract Big Pharma to South Carolina but is also in discussion with a a multi-national large laboratory corporation to eventually establish a high volume esoteric lab in South Carolina to provide high volume DNA based testing nationwide.