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Promoting a Culture of Excellence in the Clinical Research Site Community

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While all study sponsors care about quality, most care more about enrollment. Because not enough sites enroll patients and deliver clean data in a timely manner, sponsors have learned to work with sites that perform only *adequately*. As a result, sites have learned that sponsors will accept *adequate* performance. Study sponsors have thus allowed clinical research sites to develop a culture of "good enough," i.e., mediocrity. Not only that, but sponsors pay dearly for mediocre site performance, spending almost as much on monitoring the sites and cleaning their data as they pay to sites themselves. Ultimately, patients pay dearly for the resulting slow and expensive clinical development process.

Quality professionals often define "quality" as "fitness for purpose." In other words, a quality product meets the customer's requirements. In clinical research, where sponsors and CROs often accept mediocre site performance, "fitness for purpose" sets a low bar.

We can do better.

At its recent conference in San Francisco, MAGI announced the MAGI Blue Ribbon Sites program. The program's objective is to promote a culture of *excellence* in the clinical research site community by:

- Publishing a directory of excellent sites so they can grow and do more excellent research
- Facilitating collaborations and shared best practices among the members so they can become even more excellent
- Encouraging other sites to become excellent so they can join the program

The program is off to a phenomenal start, with 84 charter members.

Why Excellence?

While only a tiny minority of all sites are excellent, they have proven that excellence is a sound business model. But excellence is more than a business model — it requires commitment. A commitment to excellence is a unifying principle that can inspire a team to go beyond just doing their jobs. While a culture of excellence includes ingredients like a shared vision, mastery of roles, accountability and collaboration, the key ingredients are pride and inspiration. Clinical research is a tough, often frustrating business that needs inspiration to rise above mediocrity and deserves pride when excellence is achieved.

What Makes a Site Excellent?

Excellent sites have the following minimum characteristics:

- Experience
- Stability
- Quick study start start-up
- Access to a large patient database
- Consistently meet or exceed enrollment commitments
- Generate high-quality data in a timely manner

Excellent sites also have sterling reputations and are often members of leading site networks and/or sponsor/CRO preferred site programs.

Why Aren't There More Excellent Sites?

Depending on how you define an "active site," there are between 50,000 and 150,000 active sites in the world. At least 500 should be excellent, but that's only a tiny fraction of all sites.

To become excellent, a clinical research site has to overcome the following obstacles, among many others:

- Investing in training, technology, quality management systems, and other ingredients of excellence is expensive. However, many study sponsors treat clinical research services as a commodity. Misapplying the principles of "fair market value," they believe they have to pay all sites the same. This is like saying all cars that run should sell for the same price.
- Many clinical research personnel can barely keep up with a constant bombardment of urgent tasks, much less set aside time to improve systems and processes.
- Regulatory compliance demands attention and slows processes.
- Clinical researchers in healthcare institutions are often burdened with slow and expensive bureaucratic processes that are beyond their control to streamline.
- Many of the experienced investigators who could lead an excellent site are leaving the industry.

It is easy to criticize mediocre sites, but the road to excellence is rough, and why bother when sponsors accept mediocrity? The prevalence of "one and done" investigators indicates that the clinical research industry should be doing more to help new investigators achieve mediocrity and then develop into excellent investigators.

Membership

Excellent sites should join the program for four reasons:

- Obtain new studies, especially from smaller sponsors and CROs.
- Collaborate with other excellent sites to mutually enhance performance.
- Sharpen the industry's focus on excellent sites.
- Help drive the clinical research enterprise in a direction that makes sense for excellent sites.

Membership carries one of two obligations with financial implications. Sites can either (a) send someone to the MAGI conference every other year to help advance excellence in the site community or (b) pay modest annual dues. For organizations with multiple sites, per-site obligations scale down with size.

Why Should Excellent Sites Welcome Competition from More Excellent Sites?

There are four good economic reasons why excellent sites should encourage other sites to become excellent:

- Excellent sites have to compete on price with sites that do not invest in excellence and might not even know their own costs.
- The time and money that sponsors spend helping mediocre sites do their job — as well as opening and closing sites that do not even achieve mediocrity — is not available to pay excellent sites.

- By increasing costs, mediocre sites reduce the amount of clinical research conducted.
- We do not have even remotely enough excellent sites now.

Can Excellent Sites Work Together to Become Even more Excellent?

Based on the first meeting of Blue Ribbon Sites at MAGI's Clinical Research Conference last month, there are clear opportunities for collaboration. For example, the group started a project to define the elements of site quality management systems for different types of sites.

Another example would be to address the corrosive dishonesty in the process by which sites estimate and then commit to unrealistic enrollment targets. In the current process, sites must learn how to lie correctly about their enrollment capacity to get a study. It would be a step forward if sponsors could expect honest enrollment estimates from Blue Ribbon Sites. And then, sites should not sign clinical trial agreements (CTAs) with unrealistic enrollment commitments. If a Blue Ribbon Site does not believe it can enroll 10 patients, the CTA should state a realistic range, or say, for example, "We will make our best efforts to enroll 10 patients but can commit to only six."

Blue Ribbon Sites will be able to participate in online and in-person discussions and contact other Blue Ribbon Sites for direct communications.

The MAGI Blue Ribbon Sites Directory

The MAGI Blue Ribbon Sites Directory should be able to accept data from sites in December and open to sponsors and CROs in January. The design will evolve, but the basic process will be as follows:

- Each site will enter its basic demographic information, a detailed site profile, the therapeutic area(s) in which it performs excellent research, and the names of the investigators who perform that excellent research.
- To find sites for a study, sponsors and CROs will sign into the directory, select a therapeutic area, and then select a geographical area (e.g., a state in the U.S.). They will then be able to send a message to the sites they want to contact.
- The system will enable sites, sponsors and CROs to track and manage their activity in the directory.

MAGI will give sponsors and CROs access to the directory at no charge.

Word about the MAGI Blue Ribbon Sites program will spread quickly through social media, industry publications, word of mouth, and possibly with conference exhibit booths. As a condition of membership, Blue Ribbon Sites will display a MAGI Blue Ribbon logo on their websites. Of course, it will help if the directory actually helps sponsors and CROs find excellent sites.

How Does MAGI Identify Excellent Sites?

A site consists of a physical location with one or more principal investigators. In a hospital, a site consists of a department. Excellence is specific to investigators and therapeutic areas so, for example, a site might be excellent in CNS but not in diabetes.

There is no simple checklist to identify an excellent site, so MAGI relies on three basic types of data:

- **The membership application** provides important data about a site and shows how a site thinks about clinical research. Self-reported data is, of course, not always reliable, but is more reliable than in some other industries.
- **A strong recommendation** from a sponsor, CRO or site network that knows a site well carries a lot of weight. Current Blue Ribbon Sites can also identify sites likely to be excellent.
- **Third-party objective data** is expanding rapidly. In many cases, software and information companies already know more about certain aspects of a site than the site knows about itself. In addition, this data can validate the site's self-reported data and encourage sites to complete the application accurately.

As the program gains more members, we will experiment with site visits by current members to assess potential new members near their location. Both visitor and applicant should learn something from a visit.

However, data alone does not tell the whole story, and there might be circumstances that require explanation, so the membership committee has to weigh everything holistically and add some judgment to the assessment.

What Happens When a Blue Ribbon Site Is No Longer Excellent?

Blue Ribbon Sites should look to the program for help, not punishment. Even excellent sites can run into problems. When that happens, we expect the site (and partners) to tell us, so we can help the site develop a CAPA plan. Other Blue Ribbon Sites can pitch in to help, e.g., by providing an SOP or explaining how they dealt with a similar problem themselves. Depending on the circumstances, the site will be able to maintain its directory listing (perhaps with a note about the situation). A temporary suspension might be required. The site might choose to drop out of the program. Involuntary expulsion should be a rare last resort.

Members

Most of the 88 charter members are located in North America, but one is in Latin America and two are in Australia. Most are independent or corporate sites, but two are in community hospitals. Discussions are underway with academic medical centers to determine the criteria for excellence in that type of organization. Charter members are listed in Appendix A.

Network Partners

There are numerous site networks. They all have their own formulas and they might not even call themselves a site network. However, they all provide business development services to their members. They might also negotiate contracts and budgets, assist with patient recruiting, and perform other services.

The key difference between a site network and a study broker is that a site network has an intimate knowledge of its sites — it knows what studies the sites are currently conducting, whether a study coordinator recently left, and other information not readily available to study sponsors and CROs. In addition, site networks can advise sponsors and CROs on which sites are best for a particular study.

The MAGI Blue Ribbon Sites program is not a site network. It does not compete with site networks. The directory provides only limited information about sites to sponsors and CROs,

and passes messages along to the site's business development contact, who might be someone at their site network. Site networks play an important role in the clinical research ecosystem, and MAGI wants to support their work, not cut them out of the process.

Site networks are joining the program as Network Partners for the following reasons:

- It helps their sites develop new business.
- It helps their sites become more excellent.
- They can offer verified excellent sites to sponsors and CROs.
- They can use membership in the program as a carrot to encourage their other sites to qualify for membership.
- Their name is associated with the program through a directory of Network Partners on the Blue Ribbon Sites website.
- They have access to the MAGI Blue Ribbon Sites Directory of sites.
- They have opportunities to help steer the program and participate in discussions with members.

There is no charge for Network Partners.

The first 11 site networks to join the program as Network Partners are BTC Network, ClinEdge, Marquez Clinical Site Partners, ClinTrial Networks, Elite Research Network, GuideStar Research, HUNT Services, Insearch Group, Interspond, PCRS Network, and Trial Management Group.

Supporting Partners

There are three types of Supporting Partners: sponsors, CROs and other service providers. Organizations join the program as Supporting Partners for indirect reasons: to benefit their sites and associate their name with the program.

Historically, sponsors and CROs have closely protected the identity of their good sites. However, that philosophy is changing, for example, in a dramatic way, with TransCelerate's Shared Investigator Platform. When a sponsor or CRO recommends a site for membership in the MAGI Blue Ribbon Sites program or encourages it to apply for membership, it has decided that it will benefit in one or more of the following ways:

- Its site will become stronger.
- It will earn goodwill from that site.
- The general population of sites will improve.
- It will get expanded access to the directory
- It will associate its name with the program through a directory of Supporting Partners.
- It will be able to access additional services that the program is developing for Supporting Partners

CROs and other service providers can also promote their site information and other services through the program.

A sponsor or CRO has to ask itself whether it can really protect the identity of its good sites when, for example, a significant fraction of its CRAs leave every year to take a position at a competitor and often talk to former colleagues at other CROs. And, even if MAGI cannot identify an excellent site, that site may, very well, contact MAGI itself.

There is no charge for Supporting Partners.

The first three organizations to join the program as Supporting Partners are Acurian, Atlantic Research Group, and Bio-Optronics.

Why Should a Sponsor or CRO Use the MAGI Blue Ribbon Sites Directory?

Large sponsors and CROs have long lists of good sites but probably not enough for all their studies. The MAGI Blue Ribbon Sites directory will be a free and convenient source of sites they might not know about. Even if a Sponsor or CRO already knows about a site, the directory can confirm its excellence and perhaps provide additional or more current information about the site.

For smaller sponsors and CROs that do not actively operate a preferred site program, the MAGI Blue Ribbon Sites program can serve that function.

Sponsors and CROs that support the program's mission should use directory to make sure it survives.

How Is the MAGI Blue Ribbon Sites Directory Different than Other Lists of Good Sites?

There are a lot of lists or databases of good clinical research sites. Sponsors and CROs have lists. Site networks have lists. TransCelerate has the Shared Investigator Platform. CTMS and other technology companies have lists. Information companies have lists. IRBs have lists.

These organizations capture different dimensions of site quality and performance, often in great detail. However, none of them combine all the features of the MAGI Blue Ribbon Sites Directory:

- Consolidated data from multiple sources, including reputational information
- Larger mission of promoting excellence in the clinical research community
- Largely managed by sites
- Free access to sponsors and CROs

Service Provider Partners

Service providers that have proven themselves with member sites will have opportunities to place their products at more of the sites that lead the industry. MAGI will not take a fee for these arrangements.

Governance

Norman Goldfarb, MAGI Chairman, is leading the initiative and, for the time being, will be an *ex officio* member of the three committees: Executive, Membership and Education.

References

"What is Fair Market Value?" Norman M. Goldfarb, Journal of Clinical Research Best Practices, December 2017

Author

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Appendix A. Charter Members

ActivMed Practices & Research
Adams Clinical Trials
Adirondack Medical Research Center
Advanced Clinical Research
Advent Research LLC
Agile Clinical Research Trials
AGA Clinical Trials
AMR NOCCR-Knoxville
Artemis Institute for Clinical Research - San Diego
Artemis Institute for Clinical Research - San Marcus
Aspen Clinical Research
Atria Clinical Research
Avanza Medical Research Center
Aventiv Research
Benchmark Research - Austin
Bioclinica Orlando
Biotech Pharmaceutical Group
Bluewater Clinical Research Group
Cedar Crosse Research Center
Chicago Medical Research
Clinical Research of The Ozarks - Columbia
Clinical Research of The Ozarks - Rolla
Clinical Research Solutions - Middleburg
Clinical Trials of Florida
Clinical Trials of South Carolina
Clinical Trials of Texas
Columbus Regional Research Institute
Community Clinical Research Center
Del Sol Research Management
Desert Oasis Healthcare Medical Group
DM Clinical Research
Doylestown Hospital (Cardiology)
Dr. Anil K. Gupta Medicine Professional Corporation
E Squared Research
Elite Clinical Trials
Elite Long Beach Clinical Trials
Empire Clinical Research
Florida Premier Research Institute
Fomat Medical Research
Frenova Nephrology and Hypertension Associates
Frenova Paragon Health PC
Frenova St. Louis Regional Dialysis
Frenova Meridian, Idaho - Boise Kidney & Hypertension Institute
Fundación Estudios Clínicos
Hillcrest Clinical Research
Hope Clinical Research
Injury Care Research
International Research Partners
Irvine Clinical Research
J. Lewis Research - Foothill Family Clinic
J. Lewis Research - Foothill Family Clinic Draper
J. Lewis Research - Foothill Family Clinic South
J. Lewis Research - Jordan River Family Medicine
Jacksonville Center for Clinical Research
Linear Clinical Research
LMC Mid-Toronto
Longwood Research
Manna Research Toronto
Marvel Clinical
Milestone Research
Moore Clinical Research
Noble Clinical Research
Olympian Clinical Research
OnSite Clinical Solutions
Optimed Research
Panamerican Health Center
Phoenix Medical Research
PMG Research - Salisbury
PMG Research of Raleigh
PMG Research of Wilmington
PMG Research of Winston-Salem
Professional Research Network of Kansas
Protenium Clinical Research
Quality Clinical Research
Quality Research
Rapid Medical Research
Remington-Davis Clinical Research
Research Center of Fresno
SC Clinical Research
Suncoast Clinical Research
Suncoast Research Group
The Community Research of South Florida
The Jackson Clinic
UnityPoint Health
University of the Sunshine Coast
Upstate Clinical Research Associate
Ventura Clinical Trials
Western Sky Medical Research

