Day 1

Monday, November 2

Plenary 10:40 am – 10:55 am	**Chairman's Opening Remarks**
Plenary 11:00 am – 12:00 pm	**KEYNOTE: How COVID-19 Is Transforming Clinical Research: A Panel Discussion** The current pandemic is forcing changes and also inspiring innovations that will benefit clinical research for years to come.
Management & Professional Skills 12:30 pm – 1:30 pm	**How COVID-19 Has Taught Us to Streamline & Simplify Clinical Trial Processes** How to streamline and improve process quality.
Management & Professional Skills 12:30 pm – 1:30 pm	**Conflict Resolution** Practical methods to resolve conflicts and generate a positive outcome.
Management & Professional Skills 2:30 pm – 3:30 pm	**Crisis Management** In a crisis, leadership, strategy and execution are essential.

Special Topics
2:30 pm – 5:00 pm

Virtual & Decentralized Trial Solutions Showcase
Leading solution providers can help you decentralize and virtualize your clinical studies. (No contact hours)

Clinical Operations, Quality & Risk Management
4:00 pm – 5:00 pm

Remote Site Governance in the Age of COVID-19
How to ensure regulatory and protocol compliance with minimal site visits

Plenary
5:15 pm – 5:30 pm

Chairman's Closing Remarks

Day 2
Tuesday, November 3

Plenary
10:40 am – 10:55 am

Chairman's Opening Remarks

Regulatory Compliance
11:00 am – 1:30 pm

Site Inspection Readiness
In this session, we will examine real-world examples of common inspection findings and the importance of proactive quality assurance, continuous quality improvement, study conduct according to GCP and the development of appropriate CAPAs so you can avoid and mitigate inspection findings. Special consideration during the COVID-19 pandemic will also be explored.

Site Management
11:00 am – 12:00 pm

How is COVID-19 Changing the Site Landscape? A Panel Discussion
Powerful forces that are changing the world of research sites.

Budgets & Billing
12:30 pm – 1:30 pm

Constructive Tactics for Effective Budget Negotiation
How to speed negotiations along and achieve a mutually satisfactory result.

Special Topics
12:30 pm – 1:30 pm

COVID-19, Patient Recruitment & Retention, and the Black Experience in American Clinical Research
The Black experience with COVID-19 participation in clinical trials in the context of the polio vaccine campaign, and our shared responsibility to science and ethics in involving racially diverse populations.

Budgets & Billing
2:30 pm – 3:30 pm

How COVID-19 Has Changed Study Costs for Sites
The time and expense of conducting studies during a pandemic...and beyond.

Regulatory Compliance
2:30 pm – 5:00 pm

Master Class: Regulatory Compliance
COVID-19 & expanded access, foreign influence, impossible situations in misconduct investigations, and public health surveillance exceptions.

Budgets & Billing
4:00 pm – 5:00 pm

The Budget Conundrum: A Panel Discussion
Can we solve the budget impasse?

Plenary
5:15 pm – 5:30 pm

Chairman's Closing Remarks

Day 3
Wednesday, November 4

Plenary
10:40 am – 10:55 am

Chairman's Opening Remarks

Clinical Operations, Quality & Risk Management 11:00 am – 1:30 pm	**Assessing, Characterizing & Managing Risk in Clinical Research** To understand a risk, you need to understand severity, probability, contingencies and a whole lot more.
Regulatory Compliance 11:00 am – 12:00 pm	**Emerging Issues in Human Subjects Protection** Hard-hitting insights into emerging hot topics...and what you should do about them.
Regulatory Compliance 12:30 pm – 1:30 pm	**Informed Consent Under the Revised Common Rule** How is "key information" being presented now, and how should it be presented?
Clinical Operations, Quality & Risk Management 12:30 pm – 1:30 pm	**Implementing a Quality Management System for Sponsors, Sites and CROs** Learn how to use interwoven processes and tools, such as process mapping, gap analysis, quality metrics, risk management, CAPA and procedural documents and tools.
Site Management 2:30 pm – 3:30 pm	**Run Your Site Like a Business During & After COVID-19** Making the hard decisions needed to survive and grow.
Management & Professional Skills 4:00 pm – 5:00 pm	**Overcoming Resistance to Change** How to get the sand out of the gears.
Plenary 5:15 pm – 5:30 pm	**Chairman's Closing Remarks**

Day 4

Thursday, November 5

Plenary 10:40 am – 10:55 am	**Chairman's Opening Remarks**

Contracts 11:00 am – 1:30 pm	**Dissecting a Clinical Trial Agreement (Part 1)** Sometimes the wording does make a difference. We will examine 50 key points in MAGI's standard clinical trial agreement template. If you think you know what you're signing, think again; it's ugly in there. Have you considered this scenario… In the first hour, we will provide an introduction to CTAs. After that, the material will be more advanced.
Special Topics 11:00 am – 12:00 pm	**COVID-19 Vaccinations: Allocation Priorities, Access, Mandates, Risks, Liabilities and Other Pressing Issues** Who gets vaccinated first? Who has the right to mandate vaccination? Who pays if something goes wrong? Who makes these decisions?
Regulatory Compliance 12:30 pm – 1:30 pm	**Would You Approve This COVID-19 Study? Study Approvals at the Edge** IRB reviews of studies right in the middle of the gray area.
Contracts 2:30 pm – 5:00 pm	**Dissecting a Clinical Trial Agreement (Part 2)** Sometimes the wording does make a difference. We will examine 50 key points in MAGI's standard clinical trial agreement template. If you think you know what you're signing, think again; it's ugly in there. Have you considered this scenario…
Special Topics 2:30 pm – 5:00 pm	**Modern Patient Recruitment & Retention** Patient recruiting during the COVID-19 pandemic, marketing your site, centralized recruiting for oncology studies and using AI on voice to assess likelihood of enrollment, adherence and retention.
Plenary 5:15 pm – 5:30 pm	**Chairman's Closing Remarks**

Day 5

Monday, November 9

Plenary 10:40 am – 10:55 am	**Chairman's Opening Remarks**
Plenary 11:00 am – 12:00 pm	**KEYNOTE: Reimaging Clinical Research: A Panel Discussion** What would clinical research look like if we were inventing it today?
Budgets & Billing 12:30 pm – 1:30 pm	**Medicare Reimbursement for Clinical Trials: Rules & Consequences** CMS rules for billing Medicare...and what can happen if you do not follow them.
Contracts 12:30 pm – 1:30 pm	**Managing Risk with Contracts: Informed Consent, Subject Injury & Indemnification: A Case Study** Injured subjects deserve proper care, but who pays for it? If something serious goes wrong, look here first.
Budgets & Billing 2:30 pm – 5:00 pm	**Putting Bulling Compliance into Practice** Practical application and systems.
Contracts 2:30 pm – 5:00 pm	**Into the Abyss: Subject Injury and Indemnification** A deep dive into the subject injury and indemnification sections of clinical trial agreements.
Plenary 5:15 pm – 5:30 pm	**Chairman's Closing Remarks**

Day 6

Tuesday, November 10

Plenary 10:40 am – 10:55 am	**Chairman's Opening Remarks**
Regulatory Compliance 11:00 am – 1:30 pm	**Recent Developments in Subject Data Privacy & Security…and How to Address Them** Ongoing changes in privacy and security laws and regulations. Pitfalls and best practices.
Special Topics 11:00 am – 12:00 pm	**Are You Hearing Us? Are We Hearing You? A Panel Discussion** What sponsors and CROs need to understand about sites...and what sites need to understand about sponsors and CROs.
Site Management 12:30 pm – 1:30 pm	**Will the Fast Startups We Are Seeing for COVID-19 Studies Survive Post-Pandemic?** We have seen what is possible. Is it sustainable?
Site Management 2:30 pm – 5:00 pm	**Master Class: Site Management Innovations & Best Practices for Institutional Sites** Key performance indicator dashboards, workload estimation vs. profitability & staffing, scientific review and realigning your organization for the new normal.
Plenary Site 2:30 pm – 5:00 pm	**Master Class: Site Management Innovations & Best Practices for Independent Sites** Using technology to centralize all functions except patient visits, key performance indicators, expanding into new therapeutic areas, and a systems approach to staffing.
Plenary 5:15 pm – 5:30 pm	**Chairman's Closing Remarks**

Day 7

Wednesday, November 11

Plenary 10:40 am – 10:55 am	**Chairman's Opening Remarks**
Plenary 11:00 am – 12:00 pm	**KEYNOTE: Bringing the Patient's Galaxy of Data into Clinical Trials: A Panel Discussion** The technology exists today to pull retrospective and prospective real-world patient data into clinical trials (with patient permission) to improve efficiency, screening, safety and follow-up: feasibility, use cases, and impact.
Special Topics 11:00 am – 12:00 pm	**KEYNOTE: Bringing the Patient's Galaxy of Data into Clinical Trials: A Panel Discussion** The technology exists today to pull retrospective and prospective real-world patient data into clinical trials (with patient permission) to improve efficiency, screening, safety and follow-up: feasibility, use cases, and impact.
Special Topics 12:30 pm – 1:30 pm	**Workshop: Mindfulness Matters** Mindfulness, an excellent antidote to the stresses of modern life, is the art of paying attention to the present moment and can be brought to any moment in life.
Special Topics 12:30 pm – 1:30 pm	**Testing to the Rescue: Rapid Diagnostics and the COVID-19 Pandemic** How it works, why we need it, and what's new.
Contracts 2:30 pm – 3:30 pm	**Those Devilish Details: Key Words & Phrases in Clinical Trial Agreements** A few words can change everything.
Management & Professional Skills 2:30 pm – 5:00 pm	**From Manager to Leader** It's a different mindset.

Contracts 4:00 pm – 5:00 pm	**CTAs for Investigator-Initiated Trials** What agreements look like when the site comes asking.
Plenary 5:15 pm – 5:30 pm	**Chairman's Closing Remarks**

Day 8

Thursday, November 12

Plenary 10:40 am – 10:55 am	**Chairman's Opening Remarks**
Contacts 11:00 am – 12:00 pm	**Creating and Using a CTA Negotiation Playbook** Creating and using guidance and backup language.
Special Topics 11:00 am – 1:30 pm	**Master Course: Medical Device Clinical Research (Part 1)** EU Medical Device Regulations update, ISO 14971 risk management for medical devices, ISO 14155 2020 updates for medical device clinical investigations and postmarket surveillance.
Clinical Operations, Quality & Risk Management 12:30 pm – 1:30 pm	**Clinical Trials for Small Sponsors: A Panel Discussion** How to conduct clinical trials with limited resources.
Management & Professional Skills 2:30 pm – 5:00 pm	**Building & Sustaining High-Performance Teams** Leaders, colleagues and sponsors: High-performance teamwork drives higher-quality outcomes.
Special Topics 2:30 pm – 5:00 pm	**Master Course: Medical Device Clinical Research (Part 2)** The changing sponsor/site relationship, the Open Wearables Initiative, human factors engineering and artificial intelligence for medical devices.

Plenary
5:15 pm – 5:30 pm

Chairman's Closing Remarks