



MAGI's Clinical Research vConference — Spring 2021

April 26–29 & May 3–6, 2021

Day 1

Monday, April 26, 2021

10:40 AM **Plenary Chairman's Opening Remarks**

10:40 AM – 10:55 AM EST

11:00 AM **Plenary - KEYNOTE: How COVID-19 Has Relunched Clinical
Research: A Panel Discussion**

11:00 AM - 12:00 PM EST

The current pandemic is forcing changes and also inspiring innovations that will benefit clinical research for years to come.

12:30 PM **Budgets & Billing - Solving the Budget Conundrum in Unsettled
Times: A Panel Discussion**

12:30 PM - 1:30 PM EST

Can we solve the budget impasse?

12:30 PM **Site Management - The Evolving Site Landscape: A Panel Discussion**

12:30 PM - 1:30 PM EST

Powerful forces that are changing the world of research sites.

12:30 PM **Topic TBD**

12:30 PM - 1:30 PM EST

Several options are under consideration.

2:30 PM **Contracts - Feel the Power: Creating and Using a CTA Negotiation Playbook**

2:30 PM - 3:30 PM EST

Creating and using guidance and backup language.

2:30 PM **Special Topics - Modern Site Selection: A Panel Discussion**

2:30 PM - 5:00 PM EST

Who can you trust when the going gets tough?

2:30 PM **Special Topics - The Time Is Right: Virtual & Decentralized Trial Solutions**

2:30 PM - 5:00 PM EST

The Time Is Right: Virtual & Decentralized Trial Solutions
Leading solution providers can help you decentralize and virtualize your clinical studies. (No contact hours)

4:00 PM **Regulatory Compliance - GCP & HSP Regulatory Fine Points: A Panel Discussion**

4:00 PM - 5:00 PM EST

Here's what the GCP & HSP regs really mean.

4:00 PM **RSite Management - Ready, Set, Go! Accelerating Research Site Startup**

4:00 PM - 5:00 PM EST

Best practices for quick site startups.

Day 2

Tuesday, April 27, 2021

10:40 AM Plenary- Chairman's Opening Remarks

10:40 AM – 10:55 AM EST

**11:00 AM Clinical Operations & Project Management
New Times, New Solutions: Key Challenges for Small Sponsors: A
Panel Discussion**

11:00 AM – 12:00 PM EST

How to conduct clinical trials with limited resources.

**11:00 AM Regulatory Compliance - Site Inspection Readiness: The Decisive
GCP Challenge (Part 1)**

11:00 AM – 1:30 PM EST

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 CAPA's so you can avoid and mitigate inspection findings.

11:00 AM Special Topics - Diversity & Inclusion in Clinical Research

11:00 AM – 1:30 PM EST

Practical ways to apply diversity and inclusion principles in clinical studies and the workplace.

**12:30 PM Budgets & Billing - Medicare Reimbursement for Clinical Trials: The
Rules You'd Better Know & Consequences If You Don't**

12:30 PM – 1:30 PM EDT

CMS rules for billing Medicare...and what can happen if you do not follow them.

1:30 PM **Site Inspection Readiness: The Decisive GCP Challenge (Part 2)**

1:30 PM – 2:30 PM EST

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 CAPA's so you can avoid and mitigate inspection findings.

2:30 PM **Budgets & Billing - Putting Billing Compliance into Practice: The Work Is Worth the Payoff!**

2:30 PM – 3:30 PM EDT

This interactive program is designed for billing compliance professionals who deal with complex reimbursement issues, need to understand the latest developments, and can contribute their own front-line experiences. We will cover Medicare, Medicaid, Medicare Advantage, commercial health and insurance plans, regional CMS contractors, state-by-state laws, secondary payer strategies, physician vs. facility payments, inpatient issues, humanitarian device exemptions, electronic submissions, denials & appeals, overpayment returns, audit documentation, and information technology solutions.

2:30 PM **Special Topics - The Time Has Arrived: Patient Recruitment for Diversity & Inclusion**

2:30 PM – 5:00 PM EST

Innovations and best practices

2:30 PM **Special Topics - Topic TBD**

2:30 PM – 5:00 PM EST

Several options are under consideration.

Day 3

Wednesday, April 28, 2021

10:40 AM **Plenary- Chairman's Opening Remarks**

10:40 AM – 10:55 AM EST

11:00 AM **Budgets & Billing - Hidden Costs that Destroy Site Profitability**

11:00 AM – 12:00 PM EST

What costs do sites and sponsors incur that are not in study budgets and not "the cost of doing business"?

11:00 AM **Quality & Risk Management - Risky Business: Assessing, Characterizing & Managing Risk in Clinical Research**

11:00 AM – 1:30 PM EST

To understand a risk, you need to understand severity, probability, contingencies and whole lot more.

11:00 AM **Special Topics - Topic TBD**

11:00 AM – 12:00 PM EST

Several options are under consideration.

12:30 PM **Budgets & Billing - Constructive Strategies & Tactics for Effective Budget Negotiation**

12:30 PM – 1:30 PM EST

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

12:30 PM **Regulatory Compliance - Would You Approve This Study? Study Approvals at the Edge**

12:30 PM – 1:30 PM EST

IRB reviews of studies right in the middle of the gray area.

2:30 PM **Budgets & Billing - Budget Development & Negotiation for Investigative Sites**

2:30 PM – 5:00 PM EST

Effective budget negotiation requires preparation: knowing your costs and developing the infrastructure and methodology to consistently maximize revenues. Demonstrate value and conduct effective negotiations. Workshop is also illuminating for research sponsors and CROs. Bring your laptop for the budgeting exercise.

2:30 PM **Clinical Operations & Project Management - Revealing Questions to Ask at Site Qualification Visits**

2:30 PM – 3:30 PM EST

Going beyond the checklist to learn the truth.

2:30 PM **Quality & Risk Management - Powerful Quality Management Systems for Sponsors, Sites and CROs**

2:30 PM – 5:00 PM EST

Learn how to use interwoven processes and tools, such as process mapping, gap analysis, quality metrics, risk management, CAPA, and procedural documents and tools.

4:00 PM **Clinical Operations & Project Management - Troubleshooting Underperforming Sites**

4:00 PM – 5:00 PM EST

Finding and fixing the problems.

Day 4

Thursday, April 29, 2021

10:40 AM **Plenary- Chairman's Opening Remarks**

10:40 AM – 10:55 AM EST

11:00 AM **Contracts - Details Matter: Dissecting a Clinical Trial Agreement (Part 1)**

11:00 AM – 1:30 PM EST

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.

11:00 AM **Regulatory Compliance - Hot Topics in Regulatory Compliance**

11:00 AM – 1:30 PM EST

This advanced program is designed for clinical research professionals with responsibility for regulatory compliance.

11:00 AM **Site Management - Roll Out the Red Carpet: How to Treat Study Participants Like Valued Customers**

11:00 AM – 12:00 PM EST

What can we learn from other industries?

12:30 PM **Special Topics - Topic TBD**

12:30 PM – 1:30 PM EST

Several options are under consideration.

2:30 PM **Budgets & Billing - Medicare Coverage Analysis Out of the Ordinary**
2:30 PM – 3:30 PM EST

Finding the limits of what Medicare will cover.

2:30 PM **Contracts - Details Matter: Dissecting a Clinical Trial Agreement (Part 2)**
2:30 PM – 5:00 PM EST

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...

2:30 PM **Regulatory Compliance - Misconduct: Minimization, Detection, Investigation & Enforcement**
2:30 PM – 5:00 PM EST

4:00 PM **Budgets & Billing - Fair Market Value in Industry-Sponsored Clinical Research Budgets**
4:00 PM – 5:00 PM EST

There's a right way to use it...and a wrong way.

Day 5

Monday, May 3, 2021

10:40 AM Plenary- Chairman's Opening Remarks

10:40 AM – 10:55 AM EST

11:00 AM Plenary - KEYNOTE: Diversity & Inclusion in Action: A Panel Discussion

11:00 AM – 12:00 PM EST

Diversity and inclusion were hot topics last year. What can we do now to make them a reality?

12:30 PM Clinical Operations & Project Management - Setting Your Study Team Up for Success

12:30 PM – 1:30 PM EST

Define scope, resources, timeline, expectations, etc., before you start.

12:30 PM Contracts - Risky Business: A CTA Case Study Involving Subject Injury & Indemnification

12:30 PM – 1:30 PM EST

Injured subjects deserve proper care, but who pays for it? If something serious goes wrong, look here first.

12:30 PM Special Topics - Topic TBD

12:30 PM – 1:30 PM EST

Several options are under consideration.

1:30 PM **Special Topics - Are You Hearing Us? Are We Hearing You? A Panel Discussion**

1:30 PM – 2:30 PM EST

What sponsors and CROs need to understand about sites...and what sites need to understand about sponsors and CROs.

2:30 PM **Contracts - Into the Abyss: Subject Injury and Indemnification**

2:30 PM – 5:00 PM EST

A deep dive into the subject injury and indemnification sections of clinical trial agreements.

2:30 PM **Site Management - How Should Sites Compensate & Contract with Investigators?**

2:30 PM – 3:30 PM EST

What is legal, fair and motivating? How should RVUs be handled?

4:00 PM **Special Topics - Sticking Points in Decentralizing Clinical Trials: A Panel Discussion**

4:00 PM – 5:00 PM EST

Sticking Points in Decentralizing Clinical Trials: A Panel Discussion
Now that decentralization is well underway, where is it running into problems?

4:00 PM **Special Topics - Topic TBD**

4:00 PM – 5:00 PM EST

Several options are under consideration.

Day 6

Tuesday, May 4, 2021

10:40 AM Plenary- Chairman's Opening Remarks

10:40 AM – 10:55 AM EST

11:00 AM Budgets & Billing - Sites Literally Can't Wait to Get Paid

11:00 AM – 12:00 PM EST

Systems, processes, tips & tricks for making and obtaining timely payments.

11:00 AM Clinical Operations & Project Management - Clinical Project Management: A Skills-Based Workshop (Part 1)

11:00 AM – 1:30 PM EST

This skills-based project management workshop will provide a solid foundation for managing projects, work schedules, risks, timelines, communications and resources, as well as utilizing metrics and key performance indicators to monitor and control your projects for clinical research managers, new project managers, line managers, and others responsible for clinical research project success.

11:00 AM Regulatory Compliance - Recent Developments in Subject Data Privacy & Security...and How to Address Them

11:00 AM – 1:30 PM EST

Ongoing changes in privacy and security laws and regulations. Pitfalls and best practices.

11:00 AM Special Topics - Topic TBD

11:00 AM – 12:00 PM EST

Several options are under consideration.

12:00 PM Site Management - Run Your Site Like a Business

12:00 PM – 1:30 PM EST

Making the hard decisions needed to survive and grow.

12:00 PM Clinical Operations & Project Management - Clinical Project Management: A Skills-Based Workshop (Part 2)

12:00 PM – 1:30 PM EST

This skills-based project management workshop will provide a solid foundation for managing projects, work schedules, risks, timelines, communications and resources, as well as utilizing metrics and key performance indicators to monitor and control your projects for clinical research managers, new project managers, line managers, and others responsible for clinical research project success.

2:30 PM Site Management - Master Class: Site Management Innovations & Best Practices for Institutional Sites

2:30 PM – 5:00 PM EST

How best to address tough challenges in managing AMC and hospital sites.

2:30 PM Site Management - Master Class: Site Management Innovations & Best Practices for Independent Sites

2:30 PM – 5:00 PM EST

How best to address tough challenges in managing independent sites.

Day 7

Wednesday, May 5, 2021

10:40 AM Plenary- Chairman's Opening Remarks

10:40 AM – 10:55 AM EST

11:00 AM Contracts - Cyberliability: Procrastination Is Not a Winning Strategy

11:00 AM – 1:30 PM EST

EDC, remote site monitoring, and other digital interactions that can expose you to incalculable risks.

11:00 AM Management & Professional Skills - Transform Your Role from Manager to Leader

11:00 AM – 1:30 PM EST

Change your mindset. Change your skills.

11:00 AM Site Management - How Are Marketing & Business Development for Sites Changing? A Panel Discussion

11:00 AM – 12:00 PM EST

Getting the word out and the studies in.

12:30 PM Special Topics - Workshop: Mind Full or Mindful? Finding Space in a 24/7 World

12:30 PM – 1:00 PM EST

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.

- 2:30 PM Contracts - 12 Key Intellectual Property Provisions in CTAs**
2:30 PM – 3:30 PM EST
- Inventions, ownership, technology transfer, and common areas of conflict.
- 2:30 PM Management & Professional Skills - Conflict Resolution: Address Difficult Situations Before They Get Out of Hand**
2:30 PM – 3:30 PM EST
- Practical methods to resolve conflicts and generate a positive outcome.
- 2:30 PM Special Topics - The "Tiny Details" that Can Wreak Havoc with a Protocol**
2:30 PM – 3:30 PM EST
- What sponsors, sites and CROs should look for in a protocol.
- 4:00 PM Contracts - Gotcha! Critical Words & Phrases in Clinical Trial Agreements**
4:00 PM – 5:00 PM EST
- A few words can change everything.
- 4:00 PM Management & Professional Skills - 6 Steps to Overcome Resistance to Change...Today**
4:00 PM – 5:00 PM EST
- How to get the sand out of the gears.
- 4:00 PM Special Topics - What Really Happened? Assessing SAE Causation**
4:00 PM – 5:00 PM EST
- The nine factors in determined the causation of serious adverse event.

Day 8

Thursday, May 6, 2021

10:40 AM Plenary- Chairman's Opening Remarks

10:40 AM – 10:55 AM EST

11:00 AM Budgets & Billing - Supporting Medicare Claims with Source Documentation & Other Records

11:00 AM – 12:00 PM EST

11:00 AM Special Topics - Seamless, Paperless Clinical Research Studies

11:00 AM – 12:00 PM EST

Clinical research is eliminating paper and connecting technologies so they can talk to each other.

11:00 AM Special Topics - Medical Device Clinical Research: Hot Topics, Regulatory Updates & New Normals (Part 1)

11:00 AM – 1:30 PM EST

This interactive program is designed for medical device professionals who deal with complex issues, need to understand the latest developments, and can contribute their own front-line experiences.

12:30 PM Management & Professional Skills - Streamlining & Simplifying Clinical Trial Processes

12:30 PM – 1:30 PM EST

How to streamline and improve process quality.

12:30 PM Special Topics - Apply Health Literacy Strategies to Clarify Your Study Communications

12:30 PM – 1:30 PM EST

Engage participants by communicating complex research concepts in plain language.

2:30 PM **Management & Professional Skills - How to Achieve Exponential Performance With Your Team**

2:30 PM – 5:00 PM EST

Leaders, colleagues and sponsors: High performance teamwork drives higher-quality outcomes.

2:30 PM **Special Topics - Medical Device Clinical Research: Hot Topics, Regulatory Updates & New Normals (Part 2)**

2:30 PM – 5:00 PM EST

This interactive program is designed for medical device professionals who deal with complex issues, need to understand the latest developments, and can contribute their own front-line experiences