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# The Future of DMCs

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# Overview

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- **Pharmaceutical Industry Orientation**
- **Safety**
- **Drivers of the future of DMCs**
- **Issues that we will continue to work on as long as there is a future**

# Future

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- **Big Data**
- **Big Medicine**
- **Technology**
- **Integration of Health Care Delivery and Clinical Trials**
- **DMCs in post market not reporting to sponsors but to Big Data/Big Medicine/Health Insurance consortia**

# Ever-present issues

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- **Training**
  - Physicians
  - Sponsor staff
  - Data analysis center
- **Independence and the role of DMC Chair**
- **Blinding Policy**
- **Indemnification**

# Issues contd

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- Who does DMC report to when they are beginning to see a safety signal
- Adaptive designs—do physicians understand the implications of CHW sample size re-estimation
- Safety data that are also efficacy data/futility analysis

# Issues contd

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- Issues in multi-regional trials
- Minority enrollment
- Granularity in the huge safety table
- Role of laboratory data
- DMC budget
- DMC audits
- Internal Safety Review Committees

# Issues contd

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- DMCs have a role in advising on termination of a trial, how about a role in advising if there is sufficient data to begin a phase III trial?