A Data Monitoring Committee (DMC) is an independent group of experts, typically including clinicians and at least one biostatistician. It is charged with ensuring patient safety and protecting trial integrity. It involves the Sponsor Organization, DMC, and often an Independent Statistical Center (ISC). The DMC Charter defines roles, responsibilities, and procedures for how a DMC operates.

**Characteristics for Small Company**
- Tendency for collaborations between a diagnostic device company and a biologic start-up company
- Often R&D in orphan disease areas
- Emphasis on medicine targeted on a subpopulation of interests, thus a smaller population
- Generally one or two compounds in pipeline

**Inherent Disadvantages**
- Fewer sponsor employees - less clear responsibilities and contractual issues
- Limited financing
- Increased reliance on CROs
  - Multiple vendors involved
  - Data management, statistics, DMCs
- Survival of the company depends on the success of one or two compounds

**Characteristics for Big Company**
- Well-established internal SOPs and corporate culture
- Systematically trained workforce and personnel throughout each “node” in the process.
- By definition, more experience in all aspects of a clinical trial

**Inherent Advantages**
- Much in-house expertise
- Financing is more readily available
- Decreased reliance on CROs
- Use full-service CROs rather than niche CROs

**What makes DMC special when it comes to Small Company?**
- More cross-functional training between the CRO and Sponsor team when starting a DMC
- More communication and collaboration between sponsor team and CRO
- More reliance on CRO statistician and data group for day-to-day operations
- Recommendations often go directly to the head of the organization
- More customized DMC report due to complexities in study design and use of reports for non-DMC activities (such as data review and annual updates)
  - Challenges with limited personnel, custom reports, contractual issues, and SOPs

**Challenges and Solutions for DMC in Small Company**

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Solution</th>
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<tbody>
<tr>
<td>Limited personnel</td>
<td>Make CRO an extension of the study team</td>
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<td></td>
<td>Clear expectations and responsibilities</td>
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<td>More persistent with timelines</td>
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<td>Customized requests</td>
<td>Use existing DMC report templates for data review</td>
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<td>Utilize existing DMC reports for annual safety reports to FDA</td>
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<tr>
<td>Contractual issues</td>
<td>Initial kick-off meeting to walk through the contract details</td>
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<td></td>
<td>Continuous re-valuation of contract milestones</td>
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<td></td>
<td>Better understanding of responsibilities and expectations</td>
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<tr>
<td>Fewer SOPs</td>
<td>Allow sponsors to work under CRO’s SOPs</td>
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<td>Continual communication on processes for quality control</td>
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<td>Clear work instructions at the beginning of the DMC service</td>
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**Inherent challenges exist with smaller companies with limited resources and personnel**

**Conclusion**
- Increased Collaboration
- High-quality Charter
- More Integrity
- Successful Research

**Reference:** Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees; FDA

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The image contains a table with the following columns:
- Abstract
- Characteristics for Small Company
- Characteristics for Big Company
- Inherent Disadvantages
- Inherent Advantages
- What makes DMC special when it comes to Small Company?
- Challenges and Solutions for DMC in Small Company

The table outlines the roles and responsibilities of a DMC, as well as the challenges and solutions specific to small companies. The abstract and conclusion sections summarize the key points of the presentation.