



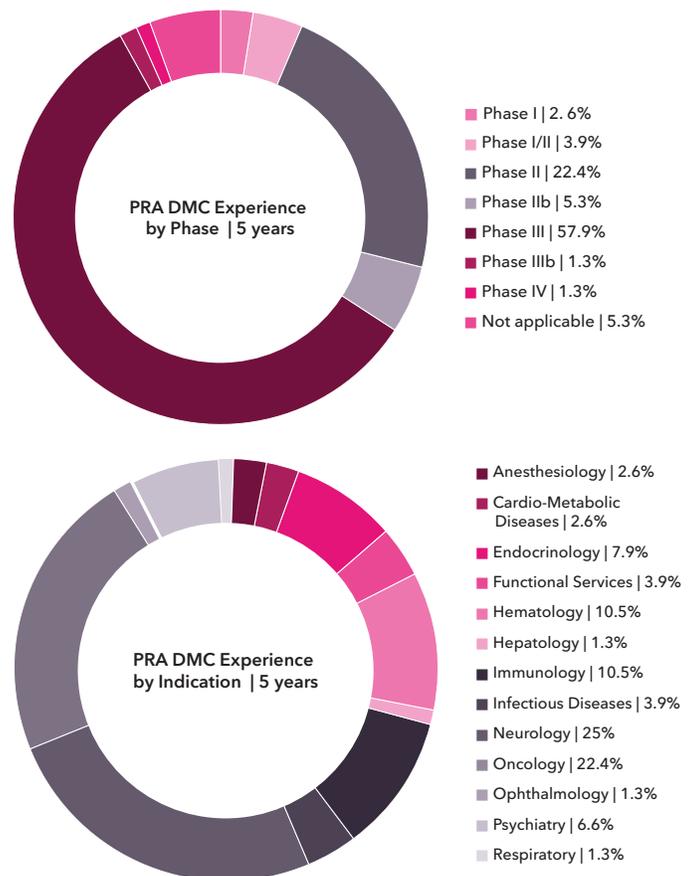
# Data Monitoring Committee Unit

Due to increasing regulatory requirements, the need for quality study and patient safety data is critical as we work together to bring our clients' novel treatments to patients. PRA Health Sciences is diligently working to meet our clients' data demands through the substantial growth of our Data Monitoring Committee (DMC) services over recent years. Staffed by a global team of experts, PRA's dedicated DMC Unit ensures our clients' projects meet the most stringent regulatory requirements.

## What is a Data Monitoring Committee?

A DMC is a team of experts who are charged with monitoring clinical trial data. Responsibilities may be limited to safety data only or expanded to include efficacy, data quality, and study operations. The term DMC may vary (DSMB, SAC, DEC) but all provide an independent review of clinical data to ensure patient safety and study integrity through interim clinical data evaluations that form a critical component of increasingly complex development programs. DMCs are used across multiple therapeutic areas and may oversee single trials, groups of related trials, or the entire portfolio of research related to an investigational product. Membership of independent DMCs may be internal, external, or a combination of sponsor/independent members, depending on the specific needs of the study.

Over the past six years, PRA has supported the planning and management and data delivery of DMCs for over 150 projects. These projects span all phases of drug development across multiple therapeutic areas.





## PRA's DMC Team: Setting The Standard In Data Monitoring

PRA offers our clients tailored DMC solutions backed by years of experience in DMC planning and support. PRA's DMC model provides the following key benefits:

### Dedicated global DMC teams:

- Strategic management and oversight for each of PRA's DMCs by Karen Shaffer, Associate Director of the DMC Unit, a registered nurse with over 15 years of experience working on DMCs and over 20 years of experience in pharmaceutical research
- DMC specialists and project managers who are 100% dedicated to DMC set-up, support, and management from start-up through close-out, including guidance on fair market value rates, Sunshine Act reporting requirements, and meeting management
- Experienced masters - and doctoral-level statisticians who can fulfill the role of independent (non-voting) reporting statisticians, advise and support DMC charter and statistical analysis plan development, and support safety and efficacy analysis and reporting to the DMC
- Statistical programmers prepare DMC-specific programs designed according to the specific needs of the protocol

### Access to a global network of independent physicians and statisticians:

As a full-service CRO, we have the technology to access physicians and statisticians from previous DMCs and our global and proprietary databases, such as:

- Member database of previous DMC members with over 850 physicians and statisticians
- Through our collaboration with the Clinical Trials Transformation Initiative DMC Project, we have relationships with DMC key opinion leaders (physicians and statisticians) and access to their findings and recommendations.

### Highly secure IT collaboration site:

In 2020, PRA implemented Box, our new enterprise document content management solution, which facilitates confidential document sharing and collaboration with internal and external parties, including external DMC members, vendors, and sponsors. Box operates as a single, unified platform to meet our document and content management needs, streamlines security and governance, and minimizes compliance risk.

As global data privacy laws require tighter securities on electronic communications, Box is also a validated, GxP and 21 CFR Part 11-compliant, single solution platform to securely author, review, and share documents.

#### Secure Box Environment Advantages

Updated and convenient file-version management, to always know when shared files have been modified and by whom

System and user-controlled access levels, allowing content access to be designated for each user, including the access level, eg, sharing, upload, download, edit rights

Quick insights into who has viewed or downloaded files

Large, secure file sharing (up to 5GB for single file uploads)

To assist your team in successfully using Box, we prepared quick system training videos, a troubleshooting guide and a Frequently Asked Questions reference, accessible [here](#). Carefully managing data privacy is our priority, and we firmly believe that Box offers a solution to help us do so.

## Next Steps

Contact Karen Shaffer, Associate Director of the DMC Unit, at [ShafferKaren@prahs.com](mailto:ShafferKaren@prahs.com) to learn more about our services or to schedule a capabilities presentation.