

Understanding Different SMO Models



Site Organization Challenges

Like many other site organizations, DaVita Clinical Research has struggled with defining ourselves within an industry that holds firm to their acronyms. CRO, or contract research organization, has been able to remain a constant within our business. No matter the service offering that a CRO may provide, they consistently claim to be a CRO.

What is a SMO?



Definition:

A SMO means a person and/or company that assumes, as an independent contractor with the clinical investigator and/or sponsor, one or more of the regulatory obligations of a clinical investigator...

A SMO can support a CRO to add confusion in how a site organization defines itself. In the industry, this classification takes on different meanings and can accommodate a variety of services and models.

CRO x SMO

Both are contractors in supporting clinical research



Contracts
with Sponsors



Legally Liable for Sponsor
Research Obligations

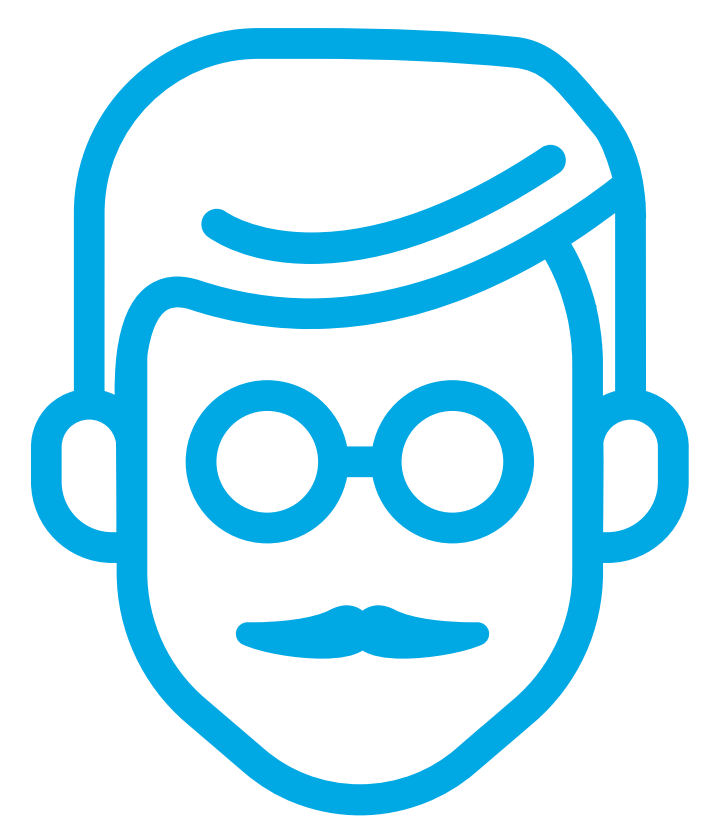


Contracts with Sponsors, CROs,
and Clinical Investigators



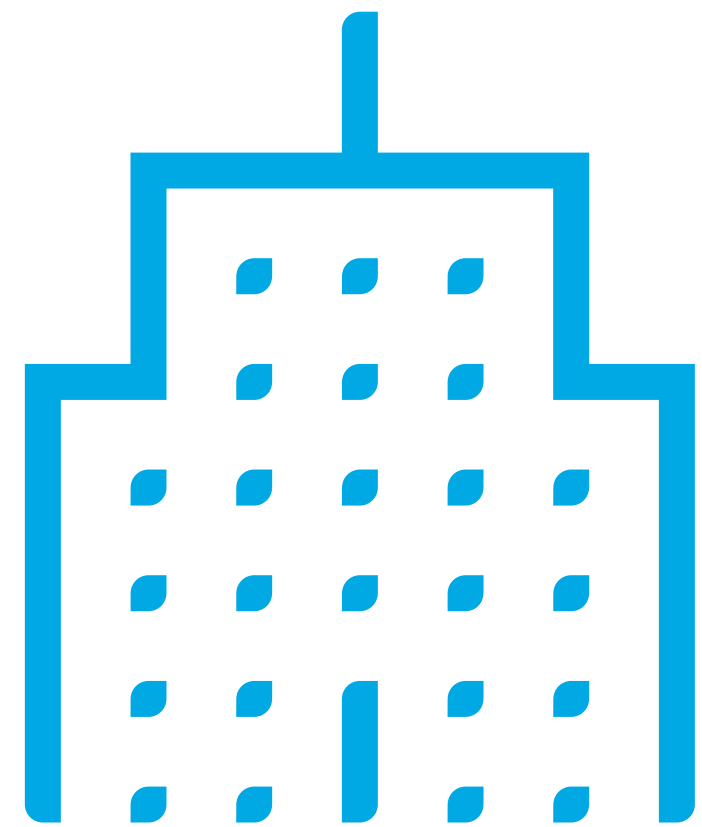
Additional Support without
Assuming Sponsor Legal Liability

Different Types of SMOs



Study Brokers

- Work with Investigators to pair with sponsors
- Do not own their facilities or procedures
- A “Middle Man”



Full Service SMO

- Own their facilities and have their own team managing the accounting for these sites
- Oversight outside of principal investigator responsibilities



Specialized SMO

- Can offer full service site management
- Focused on specific types of research