

## SMOs, TMOs, Site Networks and More!

By Nicolas Cindric

Contract Research Organizations (CROs) exist to help clinical study sponsors work with research sites and perform other study activities. On the research site side, there are comparable organizations that are referred to by the following names:

- Site Management Organization (SMO)
- Trial Management Organization (TMO)
- Investigative Site Network (ISN)
- Independent Practice Association (IPA)
- Site Alliance or Consortium
- Study Broker

There are no clear-cut definitions for these diverse organizations. As a result, organizations in a given category may offer different services, and organizations that offer the same services may categorize themselves in different categories. The purpose of this article is to bring some clarity to the various categories. To describe them collectively, we propose the term, “Site Service Organizations” (SSOs).

All SSOs are based on the premise that certain business and operational functions can be provided more efficiently on a centralized basis than at each individual site. Alignment with an SSO can also enhance the credibility and strengthen the negotiating posture of a site that does not have the presence of an academic medical center or multispecialty clinic. Many large sites have established centralized clinical trial offices to achieve similar advantages. Table 1 presents SSO examples and characteristics.

**Table 1. SSO Examples and Characteristics**  
(Key: B = Broad, N = Narrow, A = Always, S = Sometimes)

Type	Examples	Site ownership	Exclusive relationship	Therapeutic focus	Geographic reach
<b>SMO</b>	Benchmark Research, DM Clinical Research, Radiant Research	S	A	B	B/N
<b>TMO</b>	Interspond, Odyssey Research		S	B	B
<b>ISN</b>	Elite Research Network, PharmaSeek, RxTrials		S	B/N	B/N
<b>IPA</b>	Lane IPA, Pacific IPA, Sheridan Healthcare		A	B/N	N
<b>Alliance</b>	BRANY, CCFA, OsNET		S	B/N	B/N
<b>Broker</b>	Investigator Location Services, Principal Link			B	B

All SSOs share three challenges:

- Providing services that are superior in cost and/or quality to those that individual sites can provide for themselves
- Attracting and maintaining relationships with research sites that (a) find the SSO's services appealing and (b) effectively carry out the site's responsibilities in the relationship, thereby enhancing the reputation of the SSO and helping it provide better services to all its clients
- Facilitating, rather than interfering with, site/sponsor relationships

## **Business Models**

Depending on the services they provide, SSOs generate revenue in various ways, including:

- Percentage of revenue from studies
- Fee per task
- Fee for labor
- Pass-through costs
- Cost sharing based on various formulae

Except for SMOs, SSOs generally do not own research sites. SMOs should not be confused with multisite healthcare organizations that conduct clinical research as a sideline.

SMOs, IPAs and some other SSOs require exclusive relationships with research sites. An exclusive relationship is not a problem if the exclusivity is reciprocal and the site is satisfied with the services provided. A related issue is exclusivity for a specific sponsor; clinical sites may find themselves paying an SSO for studies they found themselves. Contract termination clauses should be examined carefully for continuing obligations.

SSOs operate across various therapeutic and geographic areas, which may or may not meet the needs of a clinical site. SSOs with a broad scope may provide better services because of their larger scale. On the other hand, SSOs with a limited scope may provide better services because of their narrower focus.

## **Services Offered**

Table 2 shows the services that SSOs may provide:

- Study identification. Identify research study opportunities for the site.
- Centralized administration. Coordinate study administration (documents, contracts, budgets, regulatory submissions) from a centralized office.
- Budget negotiation. Negotiate study budgets on behalf of the site with the Sponsor or CRO.
- Contract negotiation. Negotiate contract language on behalf of the site with the Sponsor or CRO.
- Regulatory assistance. Assist sites with the completion and submission of regulatory documents to the study IRB.
- Subject recruitment. Assist sites in recruiting subjects for the study, including execution of local recruitment activities.
- Call center. Manage a centralized call center to support subject recruitment activities.
- Recruiting database. Maintain a centralized database of potential subjects for upcoming studies.

- Recruiting website. Develop and maintain a study-specific website for providing information to potential subjects for a study.
- Receivables management. Manage the collection of sponsor payments and ensure that site is receiving accurate compensation for its activities.
- Ongoing study management. Provide higher-level management oversight for the study.
- PI/site training. Deliver and/or coordinate ongoing site staff training; develop and implement standard operating procedures.
- Staffing. Hire, train and compensate site employees (coordinator, regulatory, recruiter).

**Table 2. SSO Characteristics**  
(A = Always, U = Usually, S = Sometimes)

Type	Study identification	Centralized admin	Budget negotiation	Contract negotiation	Regulatory assistance	Subject recruitment	Call center	Recruiting database	Recruiting website	Receivables mgmt	Ongoing study mgmt	PI / site training	Staffing
<b>SMO</b>	A	A	A	A	A	U	S	U	S	A	A	A	U
<b>TMO</b>	A	S	S	S	S			S		S		S	
<b>ISN</b>	A	S	S	S	S	S		S	S	S	S	S	S
<b>IPA</b>	S	S	S	S									S
<b>Alliance</b>	A	S	S										
<b>Broker</b>	A												

### Site Management Organizations (SMOs)

As implied by their name, the primary role of SMOs is to provide managerial oversight to a group of sites performing research. In their infancy, SMOs usually owned or had a substantial equity stake in the sites that were part of their organization. More recently, SMOs have emerged that do not have an ownership interest in the sites but still provide similar managerial functions. Oftentimes, these services are provided to groups of practicing physicians, thereby facilitating research as an adjunct to their private practice.

Because of their broad scope of services, SMOs tend to charge relatively high fees when compared to other types of SSOs. It took a number of years for SMOs to refine their operating models, but those that exist today have successfully balanced services and costs. The SMO business model is most efficient when a high percentage of its sites conduct the same study.

SMOs generally negotiate clinical trial agreements and budgets in the role of principal, and then subcontract study conduct to their sites. As mentioned above, site participation in an SMO is an exclusive relationship. SMOs might themselves belong to a TMO or ISN, and might utilize study brokers to identify studies, but the individual sites are not permitted to maintain these relationships.

## **Trial Management Organizations (TMOs)**

The term Trial Management Organization (TMO) may have emerged as a result of some early SMOs overpromising and underperforming. Perhaps the most confusing element of TMOs comes from the name itself. Someone unfamiliar with the clinical research industry might assume that TMOs manage trials along the lines of traditional CROs, which manage trials for sponsors. Within the United States however, TMOs typically follow one of two models. In the first model, they are essentially SMOs by another name. In the second model, they operate more like a study broker, serving as an intermediary between Sponsors/CROs and sites. Unlike a broker, however, which charges an upfront fee for each study provided to a site, TMOs typically (a) charge sites an annual membership fee or (b) negotiate separate budgets with the Sponsor and Site and collect the difference as a management fee.

## **Investigative Site Networks (ISNs)**

Investigative Site Networks (ISNs) represent possibly the widest disparity of all types of SSOs. Some ISNs serve specific geographies and/or therapeutic areas, and provide a narrow range of services for partner sites. Others are much broader in their geographies, therapeutic areas, and/or services. As one might expect, when ISNs operate like SMOs, site participation in the network is often exclusive. When not operating in this fashion, participation is generally non-exclusive, and sites can participate in more than one network, TMO or Site Alliance. In general, ISNs present themselves as representing independent sites, in contrast to SMOs, which represent captive sites.

## **Independent Practice Associations (IPAs)**

An Independent Practice Association (IPA) is an association of independent physicians, or an organization that contracts with independent physicians and provides services to managed care organizations for a negotiated rate. IPAs primarily provide services related to clinical care, but some have recently branched out into clinical research. Of the types of SSOs discussed here, IPAs are the only type that is not primarily or entirely devoted to clinical research. Because of this broader relationship, research sites may find IPAs a convenient source of clinical-research-related services. It would be unusual for a non-IPA member to contract with an IPA solely for clinical-research-related services.

## **Site Alliances/Consortiums**

As implied by the name, Site Alliances or Consortiums represent groups of sites that come together to gain economies in some aspect of their business. They are similar to ISNs, but their services are generally very limited, often just to study identification. The philosophy is more of a mutual-aid society.

## **Study Brokers**

Study Brokers are probably the easiest type of SSO to define. Simply put, brokers match study sponsors and CROs with research sites for specific studies. They find studies that need investigators and then broadcast the opportunities to sites. Study brokers generally charge sites an up-front fee of 6%-10% of the study budget. However, for some studies, the Sponsor pays the fee. Others charge a monthly or annual fee for their business development services.

## **Summary**

The good news is that a wide variety of SSOs exist to serve the needs of research sites. In the absence of clear nomenclature, however, it can be difficult to determine an SSO's services and its relationship with sites. This article has attempted to bring some clarity to the various categories, but some SSOs will no doubt disagree with the characterizations above. In the absence of a clear nomenclature, development of the SSO industry will be hindered by confusion in the marketplace.

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