# Working with Academic Research Organisations (ARO’s): Some Remarks and Perceptions

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# Slide#1
# The role that ARO’s play

Disclaimer:  these observations are based purely on my personal experiences in the Pharma Industry

Definitions of ARO’s
Generally used to describe organisations that are linked or affiliated to Universities.  They are usually non-profit and their primary aim is to perform Clinical Research by conducting global clinical trials designed to improve patient care.

However, the role they play is much wider-

- They provide academic leadership.  The concept of the ARO dates back to the late 1980’s when several groups of physician investigators first came together to address unmet clinical needs by organising and centralising the operational efforts associated with conducting large multi-centre ‘megatrials’.

- Collaborate with other academic partners, regulatory authorities and industry sponsors.

- Run established network of research sites (at the larger organisations this can represent several thousands investigator sites across 50+ countries). This means ARO’s are in daily contact and much closer to the patients.

- Provide Independent analysis of data and interpretation of results.

- Share knowledge by scientific publications and presentations.

# Slide#2
# Types of ARO and some examples

There are a variety of organisations that are broadly classified under the ARO umbrella-

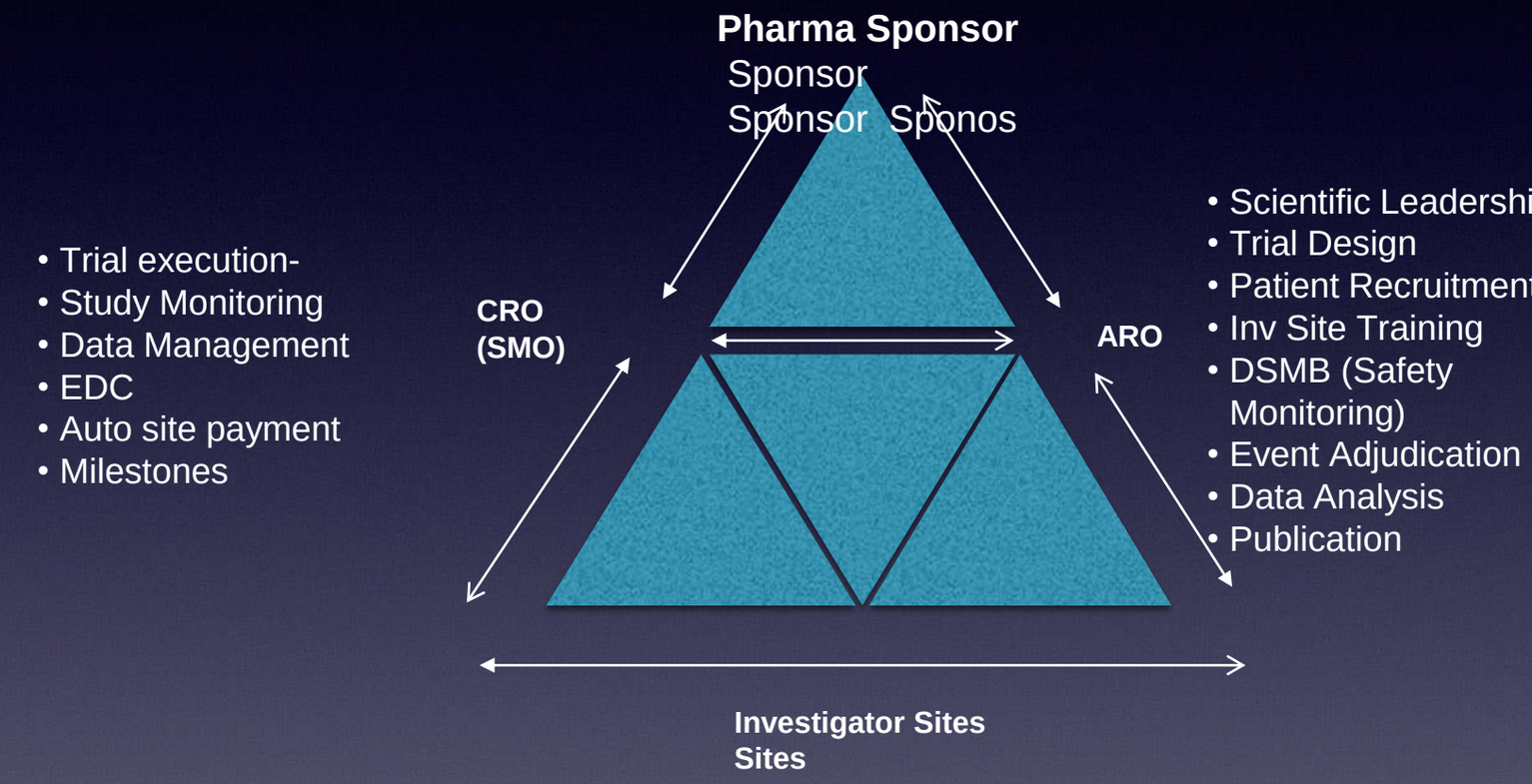
Academic Hospitals
University Medical Schools
Scientific Research Groups
Medical Institutions & Trusts
Investigator Site Networks

<u>Geography</u>
Strong focus in North America and Europe (with AsiaPacific region becoming increasingly important).

Examples of ARO's include-

- Large Universities such as Duke (DCRI), Stanford, Cincinnati and the TIMI group at Harvard in US.  PHRI at Hamilton in Canada and Imperial College and Oxford in UK.
- Scientific collaboration groups and networks such as the National Institutes of Health (NIH) in US.
- Smaller niche organisations in specialist therapeutic indications such as Colorado Prevention Centre (CPC), Mt Sinai hospital and Thrombosis Research Institute (TRI).
- Investigator site networks such as the European Network of Gynaecology Oncology Trials (ENGOT) and Gynaecology Oncology Group (GOG).

# Slide#3
# Dynamics of the ARO-CRO model in Pharma Sponsored Trials




Some points to consider -

- Pharma companies cannot work in isolation, consider novel therapies
- Working with ARO's can be complex - consider different stakeholder groups where inherent tensions may exist
- Politics and Conflict of interests
- Also consider other types of trials such as Investigator sponsored & non-interventional registry trials

# Slide#4
# Some points to consider when developing the contract

- Due diligence on new ARO’s is important
- Majority of contracts in this area are bespoke (range from SLA to MSA)
- Contract templates designed for CRO services are of limited use.  Pharma should consider using the ARO contract template?
- If study start-ip is within the remit of the agreement then time pressure may be critical.
- Costing the ARO contract may be complex and require careful negotiation.  Rate cards and unit costs (as for CRO’s) may not exist.  There may also be costs for FTE resources and institutional overheads which may mean working with ARO’s appears expensive.
- Do not forget payments to ARO’s and KOL’s may need to be recorded for EFPIA code (voluntary) and Sunshine Law in US.
- Pharma companies should shoulder some of the risk associated with performing clinical trials and this should be reflected in the Limit of Liability for example.
- Ownership of data is a key talking point.  The ARO will want to access the data for analytics and publication (and even retention in their database for commercial purposes).  This should be clearly understood at the onset and expectations set.

# Slide#5
# The Evolution of ARO’s

- The academic-industry partnership, if organised appropriately, has been proven to be a successful model, allowing exploration of novel therapies, elucidation of important mechanisms and greater understanding of critical illness.

- With greater take up of evidence-based methods of prevention and treatments from ground breaking research being quickly adopted into clinical practice, the benefits to patients are clear.

- Increasingly ARO’s are being seen as a strategic partner by Pharma, especially in Cardiology and Oncology therapy areas where there is an increased focus on accessing targeted patient populations, building efficiencies in the trial design and reducing recruitment costs.

- The emergence of data being used to predict and treat disease in targeted and specific sub-sets of the patient population.

- The construction patient databases, analytics and modelling of this data to facilitate highly specialised and personalised treatments based upon individual markers.

- Generating new data and expanding patient registries.

- Emerging healthcare technologies including the use of Artificial Intelligence, cutting edge models and pioneering global programmes.

- ARO’s will continue to play a vital role in ‘building the bridge for bench to bedside’.