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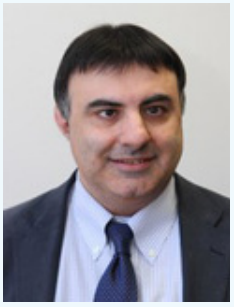
Considerations for Asia Pacific clinical trials

By Alek Safarian

As in many other industries, the emerging markets of Asia represent new frontiers for pharmaceutical and biotechnology companies. In recent years the widespread adoption of GCP across the region has meant the industry now is looking to Asia not only for clinical trials intended for local registration, but also as part of global development programs. The acceptability of data worldwide, a keen and well-qualified investigator community and sheer numbers of patients make the region a compelling choice for many drug developers.

The challenge to deliver is particularly great for smaller sponsors that may not have a local presence, or prior experience, in the region. Add to that the fact Asia is evolving rapidly to meet demand—regulators in most Asian countries are keenly aware of the importance of their role, and sponsors and vendors alike now have a much sharper focus on the region than only a few years ago when setting critical paths for their clinical development programs.



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So, what are some of the key issues in weighing up Asia Pacific clinical trials? Consider the following:

- **Regulatory considerations and startup time:** these can differ markedly from country to country.
- **Access to patients:** the conduct and scope of local feasibility can be different from western countries. This is critical in appropriate goal setting and best conducted with feet on the ground.
- **Cost:** while less costly than western countries, there is a wide variety across the region. The more developed countries such as South Korea and Singapore will have a significantly higher cost base than most of the region.
- **Commercialization:** given the rise of many Asian countries as sizable pharmaceutical markets in their own right, many developers choose to pursue a dual strategy of U.S./E.U. as well as local registration when planning trials in the region.
- **Execution:** careful due diligence on vendors takes special prominence when operating across much greater distances than the norm.