

DRUG DEVELOPMENT CHALLENGES

It's not easy developing new medicines. Teams responsible for developing new drugs face a multitude of challenges - both internal, and external...

COMPLEX PRODUCTS

Increasingly, products in development have a complex, or unusual, mechanism of action. In many cases, team members are not familiar with the underlying disease biology.



INCREASED REGULATORY DEMANDS

Authorities are demanding longer-term outcomes data, and in many cases require accompanying biomarkers. Correct patient selection is critical.

TEAM MISALIGNMENT

Greater complexity means larger teams. And team member turnover leads to loss of expertise. Result? Team members hold different views on the same product.



RECRUITING INVESTIGATORS

The ever-narrowing focus of research (e.g. oncology) means intense competition for investigators and patients. Only products judged innovative and well-characterized will be competitive.

DEMAND FOR OPTIMAL RETURNS

With research costs increasing, yet fewer products being approved, senior management demands optimal commercial success for each product approved.



MORE DRUG DEVELOPMENT CHALLENGES

As if the previous challenges weren't enough...

HEALTH TECHNOLOGY ASSESSMENT (HTA)

Many major markets now have strict HTA rules, requiring that products meet value criteria, as well as medical efficacy and safety parameters. Is the product value well-articulated?



MARKET ACCESS DIFFICULT

With the move to specialist and rare diseases, availability of epidemiology, or cost data, may be severely limited. Making it difficult to create robust cost-value models for payors.

INCONSISTENT COMMUNICATION

Large team, plus changing membership, plus complex product, plus silo mentality, gives rise to inconsistent communication. This dilutes the scientific story and its associated value.



BUDGET CUTS

High-priority products overrun their budgets, leading to budget cuts for other pipeline products. Decisions on budget cuts are often made on the basis of poor, or incomplete, information.

RISK MANAGEMENT

Inconsistent communication creates possibilities for confusion and misinterpretation - both internally, and externally. This creates additional, unneeded risk.

