Putting the "e" in PATIENT-REPORTED OUTCOMES

Trending now: Electronic data collection improves data quality, shortens study timelines, and increases the likelihood of regulatory approval.

ALTHOUGH transitioning from a pen-and-paper strategy to an electronic patient-reported outcome (ePRO) approach requires a costly initial investment, the benefits of investing in ePRO technology yield long-term results, according to Cutting Edge Information.


Jason Richardson

As clinical teams and study participants adopt tablets and other mobile devices, data can be entered more uniformly, and secondary data entry into a central database is unnecessary. Patients using ePRO instruments are not allowed to skip questions or answer in a different format, and clinicians collecting and recording data do not risk errors in entry.

"Employing ePRO technology streamlines data entry and reduces the risk of error associated with manual practices," says Jason Richardson, president and CEO of Cutting Edge Information. "These improved practices lead to better data, shorter study timelines and a greater probability of approval."

Turnover and Protocol Noncompliance Plague Site Landscape


Ken Getz

Global clinical trial performance and efficiency are hampered by high turnover and noncompliance among principal investigators and wide variation in investigative site experience, according to an assessment by the Tufts Center for the Study of Drug Development.

While the number of investigators globally now stands at about 40,000, a record half of them were new to the job in 2013, the most recent year for which data are available, according to Tufts CSDD.

In addition, although the highest turnover rates are observed among the least active investigators, turnover rates have been getting progressively worse among more active investigators.

At the same time, protocol noncompliance, the most common performance deficiency and one that has grown the fastest during the past decade, accounted for 46% of all investigative site deficiencies.

"Operating conditions for clinical trials have noticeably worsened in recent years," says Ken Getz, associate professor and director of sponsored research at Tufts CSDD. "Most frustrating for drug sponsors and contract research organizations looking to achieve higher levels of predictable performance is the wide variation that exists in the infrastructure, stability, and experience levels of investigative sites conducting clinical trials globally."

He also notes that the global investigative site landscape remains highly fragmented with no indication that it will consolidate and begin achieving scale efficiencies soon.

CRO Market Expected to Grow

The global CRO market is expected to grow at a CAGR of 9.83% over the period from 2014 to 2019, according to Infiniti Research Limited. Increased outsourcing of R&D activities by global pharmaceutical and biopharmaceutical vendors is one of the main drivers of the market.

Several tier I and tier II pharmaceutical and biopharmaceutical vendors are outsourcing R&D and clinical trial activities to CROs to reduce their expenditure on R&D activities.

Further, the shortage of experienced personnel to conduct various activities in CROs is one of the main challenges in the market. Moreover, many CROs do not have sufficient personnel to fulfill the R&D demands of several vendors. PV

Therapeutic trax

Anemia

The global erythropoietin (EPO) market is expected to reach $11.9 billion by 2020, with CAGR of 9.7% from 2014 to 2020. Darbepoetin alfa is the fastest-growing drug class at a CAGR of 12.9% during the forecast period, because of its high potency and minimal side effects. Rising incidences of cancer, end stage renal disease, and HIV have largely contributed to the demand for EPO drugs. About 20% of the patients suffering from cancer/HIV and 70% of the patients suffering from ESRD undergo chemotherapy.

Source: Allied Market Research

Autoimmune

The global rheumatoid arthritis (RA) market value will witness steady growth, from $15.6 billion in 2013 to $19.3 billion in 2023, at a CAGR of 2.1%. Of the 10 major pharmaceutical markets (the U.S., France, Germany, Italy, Spain, the UK, Japan, Australia, China, and India), the U.S. boasts the largest RA treatment, with a 67% share in 2013.

Source: GlobalData

Cancer

The value of the non-Hodgkin lymphoma market is expected to reach $9.2 billion by 2020 from $5.6 billion in 2013 at a CAGR of 7.4%. The expected launch of promising drugs, including novel small molecule inhibitors and next-generation monoclonal antibodies, as well as the continued use of the current blockbuster, Rituxan/ Mabthera (rituximab), will be the key growth drivers.

Source: GBI Research

Diabetes

The type 2 diabetes treatment market in Asia-Pacific (APAC) will rise in value from an estimated $6.5 billion in 2013 to $10.5 billion by 2020, representing a CAGR of 7.1%. Of the four major APAC countries, China will see the fastest expansion, with a CAGR of 11.1% over the forecast period.

Source: GBI Research