Journal of Applied Pharmacy
ISSN: 1920-4159
OPEN ACCESS Freely available online
Commentary

Evaluation of Patient-Reported Outcomes in the Approval of New Cancer Drugs

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DESCRIPTION

Healthcare specialists and regulatory bodies realize the importance of Patient-Reported Outcomes (PROs). PRO Measures (PROMs) can be used to supplement the evaluation of disease-related symptoms, psychological and social functioning, therapy-related adverse events, and treatment satisfaction. Cancer patients who report PROs can engage more actively in their treatment and give crucial references for clinicians' decision-making. In the clinical practise of oncological departments, it is critical to prolong survival and improve the Quality of Life (QoL) of cancer patients. PROs can accurately represent QoL and other patient experiences. HRQoL and other patient-reported outcomes in cancer trials might offer significant data to aid in assessing the risks and benefits of treatment and promoting patient-centred cancer care.

While quality of life is becoming important in the treatment of cancer patients, current oncology medication approvals are still mostly based on survival-related endpoints. A considerable number of novel cancer medications have been released in recent years, frequently based on their use of Overall Survival (OS) as the gold standard for therapeutic benefit in oncology patients. Various licensed cancer medications did not provide high clinically relevant improvements in terms of Qom or OS in post-marketing clinical practice compared to placebo or per-existing regimens, according to various recent assessments of the post-marketing clinical value of oncology therapies in the literature. Several studies have found that many cancer medications do not deliver adequate improvements in Qom or that there are several flaws in Qom measurement in oncology clinical trials.

From a regulatory standpoint, the notion of patient-focused drug development is broadly acknowledged, with Patient Experience Data (PED) serving as the primary gateway. PRO is one of the important presentations in PED, which relates to all information about patients' experiences, views, and preferences on the disease and accompanying therapies. The need for PROs to aid in the development of innovative cancer treatments has grown as international drug regulatory bodies have become more interested in investigating patient-focused medication development. Sponsors and regulators were more interested in how patients perceived illness situations and treatments.

Many regulatory organizations, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), are investigating how to include patient experiences and viewpoints into medication development. The US Food and Drug Administration (FDA) has approved the use of Pros as clinical trial endpoints in the development of cancer medicines and biologic. The FDA has issued a set of guidelines to help with patient-centered medication development.

However, there are difficulties in collecting, analyzing, and interpreting Pros. Previous study has found that Pros are rarely included in the labelling of FDA-approved cancer treatments, and regulators' views on PRO outcomes remain ambiguous. There is not enough clarity on how PRO is utilized to guide benefit-risk evaluation and regulatory decision-making in innovative cancer product applications, and existing Proms in the oncology area have substantial obstacles in playing a meaningful role in marketing. The design and implementation of PROs in clinical trials, and worldwide guidelines for PRO inclusion and analysis are being established.

Nonetheless, studies that comprehensively examine regulatory concerns remain few. Drug price changes should focus on the cancer premium in order to increase patient access to cancer medications while also achieving fairness across therapeutic areas and sustainability in health care systems.

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Received: 22-Jun-2023, Manuscript No. JAP-23-25253; **Editor assigned:** 26-Jun-2023, Pre QC No. JAP-23-25253 (PQ); **Reviewed:** 10-Jul-2023, QC No. JAP-23-25253; **Revised:** 17-Jul-2023, Manuscript No. JAP-23-25253 (R); **Published:** 24-Jul-2023, DOI: 10.35248/1920-4159.23.15.364

Citation: Amano M (2023) Evaluation of Patient-Reported Outcomes in the Approval of New Cancer Drugs. J App Pharm. 15:364.