Adaptive Pathways and Real-World Evidence: Three Perspectives

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Real-world evidence (RWE) is becomingly increasingly accepted as a valuable source of evidence supporting decisions about the use of medicines, but there are still significant challenges in achieving widespread acceptance and use of RWE.

Despite this, many pharmaceutical companies are not re-thinking the assessment of value of therapeutic innovations, focused instead on tweaking the traditional model of clinical trials and other approaches. This is not the time to be complacent. The future will be a world in which RWE is used to inform decision-making.

One of the key issues is the alignment of RWE with traditional sources of evidence. While this may make sense in a world where we have a single payer and a single decision-maker, this is not the case in most countries. In addition, the use of RWE is often limited to special cases, where there is a high unmet patient need, or an urgent medical need, such as orphan drugs.

Patients equally have a role in defining the value of an innovation, in line with the principle that ”the patient is an active participant in his or her own health care. This is a key issue, while stakeholders can generally agree on the importance of patient involvement, there is less agreement on how this should be implemented.

There is a need for more systematic approaches for effectiveness planning, incorporating real-world evidence, which is becoming quickly outdated in this highly dynamic environment. This includes engaging earlier in scientific advice processes, demonstrating benefit/risk and value in the challenging environment of orphan drugs, demonstrating benefit/risk and value in the challenging environment of orphan drugs.

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