

# Physician Views: Expanded access in cancer – how are oncologists utilising this opportunity?

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## Abstracts

According to analysts at Barclays, oncology continues to attract around one-third of pharma's total R&D investment. This trend is driven by a number of factors, not least the commercial opportunity afforded to a disease area where unmet need remains high. However, in addition, regulatory and healthcare provision architecture around cancer products affords developers both the opportunity to secure expedited approval and access a larger number of patients prior to regulatory clearance or launch.

Last month, the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) announced the soon-to-launch 'Early Access to Medicine Scheme' (EAMS), a system which has drawn comparison to the FDA's 'breakthrough therapy' designation and which can be expected to attract its fair share of applications from cancer drug developers - ViewPoints: The UK's 'early access to medicine scheme' – close cousin or distant relative to FDA breakthrough status?

Such a framework also includes expanded access – or named patient – programmes that allow for the use of experimental therapies prior to approval and outside of the clinical trial setting, often in conjunction with patient advocacy groups and regulatory agencies. There could be potential disadvantages in allowing early access to a new cancer product, but a number of developers have also highlighted notable benefits derived from the process.

To assess the view of expanded access programmes from the position of the physician community, FirstWord is polling oncologists based in the US and EU5. Specifically we are asking them

How aware they are of expended access programmes?

What they perceive to be the key benefit of expanded access programmes?

What key concerns they have about expanded access programmes?

What issue with expanded access programmes needs resolving the most urgently?

Which stakeholder will play the most important role in driving wider adoption of expanded access programmes?

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