What are the biggest issues in drug discovery and development?

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More incentives to discover and develop innovative treatments. Enabling companies to work together more easily. Flexible pricing for new medicines.

Improving the creation and use of biomarker tests, and new indicators of

effectiveness to speed up clinical trials.

These are all essential measures to improve the current system for discovering and developing new cancer drugs, in our view here at The Institute of Cancer Research, London. There is now growing consensus of the need for these changes in the wider sector too, across the academic, charity, pharmaceutical and medical sectors.

Finding consensus

The ICR has played a leading role in seeking consensus over the past year, as we have worked with peer organizations to agree a series of statements for how to widen access to innovative cancer drugs.

We released the first set of consensus statements today following a summit last year, which brought together key representatives of organizations across the sector—from charities Cancer Research UK and Breast Cancer Now, to sector organizations the Faculty of Pharmaceutical Medicine and the Ethical Medicines Industry Group, to a range of pharmaceutical companies—to find ways to address the high costs of cancer drugs and increase their availability to patients.

The ICR has long been a leading voice in campaigning for changes to the systems governing drug pricing and access, which are not set up to bring the benefits of new treatments to patients as quickly as they should.

And the statements released today—covering issues from the importance of innovation, to variable and 'outcome-based' pricing models—lay out a series of measures which, given action, could dramatically improve patients' access to new drugs.

Innovation

As an innovative research organization, we believe that innovation should also be taken into account in drug approval and pricing.

We need NICE to take greater account of a drug's degree of innovation when deciding whether to make it available on the NHS—to reward companies for taking risks in drug discovery and development, and to ensure the most exciting new drugs reach patients more quickly. "We believe a drug's degree of innovation in its mechanism of action should be properly considered when evaluating new treatments for use on the NHS," the consensus statement says.

Pricing and access

Systems around pricing also need to change to give patients better access to medicines. One change that could have a big impact would be to allow 'variable' pricing, with different prices agreed for drugs depending on which conditions they are treating.

At the moment, a company will usually first bring a new drug to the market for the condition for which evidence of benefit is strongest. But it can be harder for companies to demonstrate that the same treatment is cost-effective for further conditions where the evidence of benefit is not quite so strong.

To be cost-effective, a company might need to consider a different price for the drug—but at the moment price changes must be done across the board, including for the first condition where the evidence of benefit is stronger.

Companies are generally unwilling to reduce the price of marketed drugs where there are already strong sales—and that can mean that patients miss out on the chance to benefit from a drug for the full range of conditions that it could potentially treat.

Prescription infrastructure

NHS prescription infrastructure needs to be improved for such a change in the way drugs are priced to become possible, as the consensus statements say. Currently, the NHS doesn't generally record the condition for which a drug is prescribed.

New rules to allow variable pricing would also need to be accommodated in the next Voluntary Scheme for Branded Medicines Pricing and Access agreement between the Association of the British Pharmaceutical Industry (ABPI) and the Department for Health and Social Care.

Other measures set out in the statements will be familiar to followers of the ICR's campaigning work. We say that we need to identify measures in clinical trials that can predict a benefit in overall survival, so results can be reported more quickly.

As the consensus document says: "We believe the public and private sectors should collaborate on dedicated research to investigate the accuracy of surrogate measure in predicting future survival benefit."

Biomarkers

One of the statements also relates to biomarker development—a particularly complex issue: "We believe diagnostic tests for biomarkers are key to advancing precision medicine and want to see them used as standard with new targeted treatments."

And that's why we are gathering experts across different sectors together again—today—for another event. Our Autumn Forum will focus specifically on finding areas of consensus that could enable the greater use of biomarker tests on the NHS.

Biomarker tests tell doctors whether a patient's disease has traits that can be treated by a precision medicine, or perhaps give an early warning of whether or not a drug is working. They look for a specific characteristic—such as a genetic mutation or a molecule circulating in the blood—that indicates potential sensitivity to a treatment.

Biomarkers are going to be essential for the development and use of new targeted cancer drugs—by helping doctors to give patients the right treatment at the right time. But we worry that there isn't enough funding and aren't enough incentives to ensure high-quality biomarkers are identified when new drugs are discovered and developed.

Clinical trials

The system for regulating clinical trials that measure biomarkers is also complex and potentially onerous. The ICR would like to see a distinction made between exploratory research to identify biomarkers, where regulations could be lighter touch, and the actual use of biomarkers in clinical trials to guide patients' treatment, which of course needs to be more tightly controlled.

We're pleased that our Autumn Forum will again share views and perspectives from across the life-science ecosystem—from charities, higher education institutions, policy makers and companies. We may represent different parts of the sector, but we are all united by a drive to benefit patients, and I'm optimistic that we will again be able to achieve consensus in recommending a way forward.

Advancing precision medicine

Today's Autumn Forum will bring together our researchers with representatives from across several sectors, including industry figures

and regulatory professionals. We'll explore in detail how to improve access to biomarker tests.

Look out over the winter for more news on the big issues raised at the Autumn Forum, and how we recommend that the systems governing the use of biomarkers in treatment should change—ultimately, to improve patients' access to the most effective new treatments.

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