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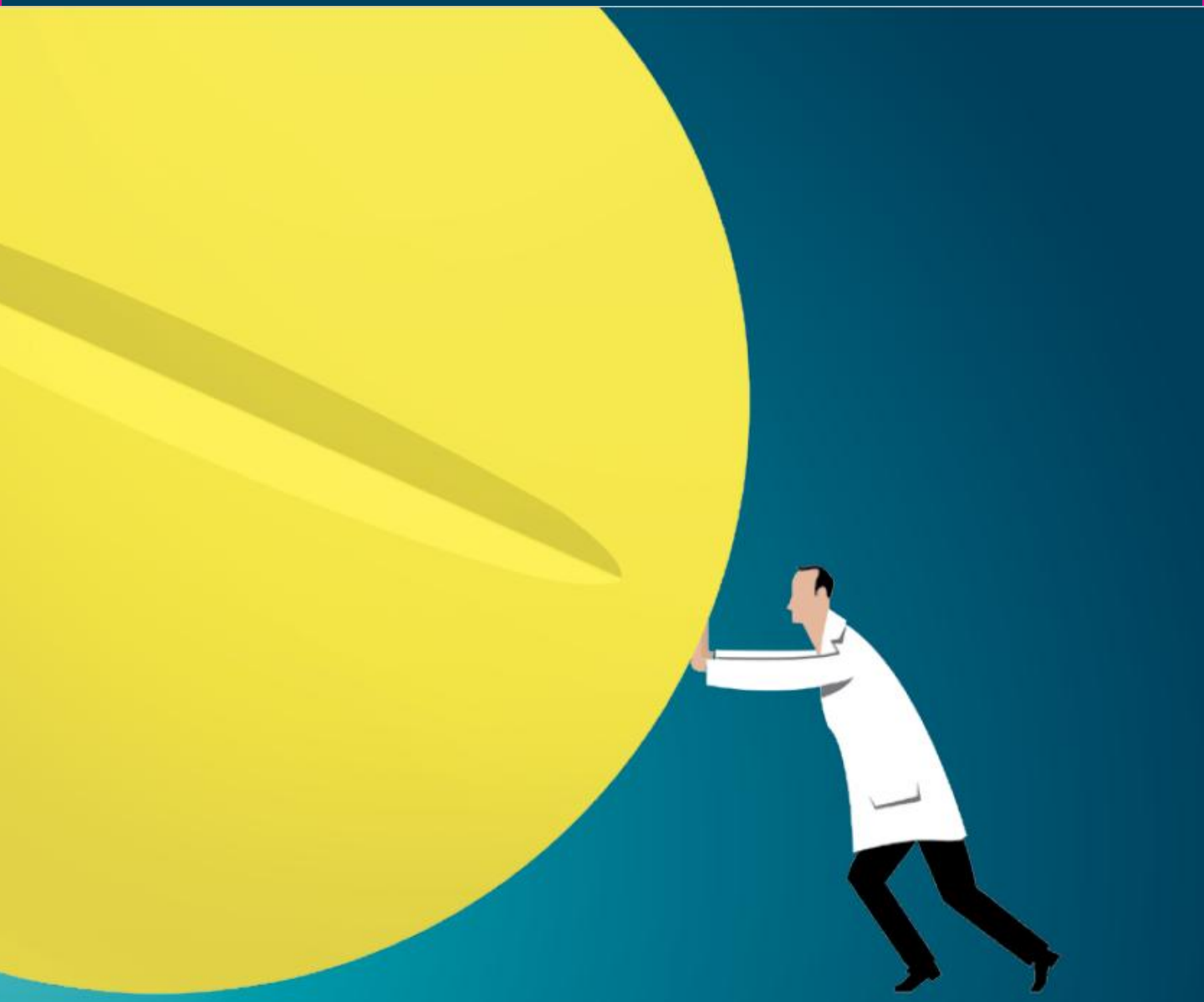
CCBIO on Ethics

Today, less than 1% of researched cancer biomarkers make it to clinical practice. There are several reasons for this, ranging from the complexities and uncertainties characterizing this field, to methodological shortcomings, or indeed the complicated relationship between Big Pharma and public cancer biomarker research.

Big Pharma can be an efficient incubator for innovative ideas from public research, and help bring cancer biomarkers to their commercial end, and to the patient's side. While public research is about scientifically discovering biomarkers, Big Pharma, with its financial resources, its 'pharmaceutical manpower' and its large-scale platforms, is more about testing and validating biomarkers on tens of models and on hundreds of thousands of samples. In this way it provides a solid basis to move on to clinical trials, and then, to governmental approval for clinical practice.

But this relationship is complicated. Indeed, the interests, values and underlying principles of Big Pharma, as a for-profit industry, are often different from the values of medical practitioners and researchers who are close to the clinical reality of the patients. While the research community may see a particular biomarker as indispensable for a sub-group of patients, Big Pharma must weigh this up against economic considerations and risks.

This relationship is also complicated by the different specificity at which public research and Big Pharma operate. As a cancer biomarker becomes more specific in its application and its role, it will likely be more scientifically robust and efficient for a particular subgroup of patients. But, in parallel, there is a



risk that this biomarker becomes an orphan test. However, a number of pharmaceutical industries prefer to focus on tests that are done on a large number of people, such as diabetes or asthma tests, and very specific cancer biomarkers would not be fitted to their large-scale validation platforms.

There are also incompatibilities related to timelines. While academics want to publish, Big Pharma often wants to keep the research secret as long as possible. There are no standard procedures for such cooperation; it works through negotiations to arrive at a legal contract.

Finally, the question of power and influence also remains a bone of contention between these groups. In entering into a relationship with Big Pharma, it becomes more likely that public research will be influenced by external agendas. Interests such as profit, patentability, marketability, or the image of the pharmaceutical company can distort the objectivity of the research, without necessarily making it 'bad science'. The relationship is not one between two equal parties; there is a significant asymmetry in power. Though the public research community can claim some power over the knowledge of biomarkers, Big Pharma can draw on deep reserves of political and economic power.

In the field of cancer biomarkers, the relationship between public research and Big Pharma is quite new. Like all new relationships, it is both exciting and frightening, and both partners should be clear about what they bring to, and want from, this relationship; whether just a marriage of convenience or something more profound. ••