Anonymous – Response 3

CDx identification guide
[redacted] welcomes the proposed inclusion of a CDx identification guide to support Sponsors in determining the need for CDx testing when submitting an application for a medicine. There is however some confusion as to the differences between the bottom two largest blue boxes in the guide, and therefore we request the TGA to clarify these further.
Companion testing plan
[redacted] has concerns that the companion testing plan may raise challenges for drug makers as they will become too dependent on IVD providers, who are often different commercial entities. Similarly, IVD companies will also be dependent on drug makers for clinical samples to validate their tests. Consideration should be made to the use of validated laboratory-developed tests to ensure optimal access for patients to testing in an optimal fashion and ensure any use of a testing plan allows for commercial flexibility between independent drug makers and IVD providers. [redacted] has concerns that the testing plan may be considered as additional regulatory burden to maintain during the lifecycle of the registration of the product, and should therefore be implemented with flexibility in mind. There are potential unintended consequences that could result in reduced/no access to innovative medicines if changes to testing plans are required to be evaluated under the standard Category 1 application pathway. It is also important to recognise that the use of overseas testing may often be used in situations to accelerate local access to innovative medicines whilst local testing is being developed. The Guideline alludes to the TGA using the testing plan to evaluate such overseas testing, which could result in additional unintended consequences for local supply. Consideration should be made to the balance between the need to ensure testing performance compared to additional red tape, and potentially exceptions could be made in cases where the trial assay or subsequent test is registered for use with the proposed medicine in a Comparable Overseas Regulator market.
Case studies
[redacted] is of the opinion that a case study clearly demonstrating how a drug maker, who may not have access to or plans to register their own IVD in Australia or may not have developed their own IVD, could identify and support local laboratories testing implementation and validation, would be useful.
Further feedback
[redacted] supports Medicines Australia's submission to this public consultation. [redacted] is supportive of the TGA's vision to provide clarity to the current guidelines, but wishes for the TGA to consider scenarios whereby the medicine Sponsor does not have access to or plans to register their own IVD in Australia.