tunity to provide additional data where there were gaps, inconsistencies identified, or clarifications necessary.

Data availability
Companies are sometimes unwilling or unable to disclose commercially sensitive data, or, if they do, may do so only partially. For example, the full contents of voluntary licences are sometimes not shared, nor the content of R&D contracts. Occasionally, where sensitive data could be analysed, complete results could not be published due to legal constraints related to public disclosure (e.g., price data). In other cases, collection of very specific data (e.g., volume of sales data for different sectors within a country) which may require disaggregation, or country-level collection, was not always possible. This issue remains an obstacle to finding and reporting reliable trends and very specific relationships and conclusions in several areas.

Additionally, in some areas it may not be possible to provide a complete picture of the area of analysis due to external constraints on the collection of data. For example, in 2016, settlements and judgements regarding breaches which occurred an where in the world were counted when evaluating companies in the areas of ethical marketing, corruption and anti-competitive behaviour. Some breaches occurred prior to the period of analysis. Even given this expanded scope, it is not possible to be confident that all breaches were captured. Sources of data collection include Lexis-Nexis, the websites of government departments such as the US Department of Justice, and registers maintained and published by a selection of industry self-regulatory bodies: the UK, the Netherlands, South Africa and Australia. Even given the significantly expanded scope of investigation, we acknowledge that breaches may have occurred which were not captured. We continue to acknowledge that breaches in Index countries are likely to be under-reported. Similarly, a complete picture of breaches of clinical trial conduct is difficult to capture, due to the absence of a central registry of such information, the fact these incidents are typically not routinely monitored by research ethics committees, and tend not to be prosecuted.

Measuring Outcomes and Impacts
The study as currently designed is not intended to measure the direct impact of companies' access initiatives on patients and other groups. For example, within Capacity Building, the impact of a company's training activities is not measured, although the Index may consider whether a company measures the impact of its own activities. Alternative measures are used as proxies for patient access or considerations of impact. For example, within Pricing, Manufacturing & Distribution, disclosure of the volume of sales achieved to different sectors within a country is taken as a proxy measure of the success of an equitable pricing strategy in being implemented.

Identifying best practices & innovations

The diffusion of best practices is one of the Access to Medicine Index's mechanisms for supporting the pharmaceutical industry to achieving greater access to medicine. Similarly, recognising those companies trialling or scaling up innovative unique-in-industry policies or initiatives is an important way of acknowledging those companies prepared to stand out from peers and to risk new approaches.

Best practices
Best practices are ones that can be accepted as being the most effective way of achieving a desired end, relative to what the industry is currently doing in that area and what stakeholder expectations are. It can also be described as a benchmark. Best practices are not new practices – they have already been conceived of, applied, and have proven to meet at least some of the following criteria:

- Sustainability,
- Replicability,
- Alignment with external standards/stakeholder expectations,
- Proven effectiveness.

In different areas of analysis (for example, in Research & Development vs. in Pricing Manufacture and Distribution) how a best practice is identified may be different. A best practice need not be unique amongst companies. A best practice might be an example of a 'gold standard' of practice; a best-in-class policy; or a strategy, programme, product initiative or group of behaviours closely aligned with stakeholder expectations. Best practices should be considered as the best practice identified by the Foundation's research team amongst the 20 companies in the submitted data, within the current period of analysis.

Innovations
Innovations have been defined in successive iterations of the Access to Medicine Index as: "a novel activity/business/model/policy/strategy being piloted/trialled by companies, which (where relevant) has evidence of financial or personnel resources invested in it (as proof of implementation)."

Innovative activities are often (but not always) unique amongst the set of 20 companies. An exception to the requirement for uniqueness is when multiple companies jointly co-operate in the same innovative activity. For 2016, the definition of Innovation was expanded to include scaling up. Therefore, a practice which was being newly trialled/piloted in the previous Index cycle, where evidence is shown that it has been scaled up, or expanded, can qualify for further recognition as Innovation in the subsequent cycle. Previously, this was limited only to Innovation in business models, within General Access to Medicine Management. Best practices, by their definition, cannot be considered innovations.

Process
To determine which of the company's practices would be highlighted as best practice or innovative, the Foundation's research team evaluated all aspects of company practices, compiling those that met the above criteria, with additional criteria for each Technical Area, where necessary. For innovative activities, special note was taken of activities submitted by companies as being considered innovative. Innovative activities could also be identified outside of that subset. The team met twice during the scoring and analysis period to agree which practices to define as best or innovative. Best practices and innovations were tested with members of the Technical Sub-Committees where relevant.