Evaluate’s Custom Solutions team supports clients across the pharma industry to make informed asset and portfolio decisions based on robust, data-driven analysis and insights. We leverage the full suite of Evaluate’s data platforms and unique metrics to support our projects. In this paper we will discuss asset valuations in healthcare, including:

- How to build a healthcare asset valuation / what you should look for in a robust valuation.
- Impact of quality inputs – patients, price & share – the three fundamentals.
- Capturing & reporting risk, sensitivity & probability.

Healthcare is a heavily specialist arena and it is not always obvious how an asset should be valued. Creating valuations or forecasts that are fit for purpose, appropriately detailed, and represent an accurate consideration of true drivers of the market is both an art and a science.

Since it can be so difficult to understand what a valuation should be based on and include, we break the valuation down in to its constituent parts so that you can check what has been included vs. what should be included. Very broadly, any valuation should take into account income and expenditure: these concepts are discussed alongside the quality or level of detail that can be covered and would be expected as part of such a valuation project.
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Building a robust asset valuation

Expenditure

This will mostly be focused around the cost of the R&D for the asset. Depending on how far through the process the asset is, the amount of spend can vary substantially.

Estimating spend on clinical trials

This is quite a tough area to estimate, however there are industry benchmarks and datasets that can be applied to help estimate what costs could likely be. We leverage unique Evaluate Omnium R&D cost metrics to incorporate highly granular indication-specific costs in our models.

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**STEP 1**
Identify the therapy area / indication of focus.

**STEP 2**
Find any other assets that are being developed for the same or a similar target audience. In our models, we leverage extensive EvaluatePharma pipeline and archive data to mine for the most directly relevant analogues for analysis.

**STEP 3**
Find the clinical trial parameters for the comparator product – specifically these should be patient enrolment numbers, phase of development and duration of phase.

**STEP 4**
Map out what you think a realistic clinical development pathway could look like – including information gathered in Step 3 above. We apply Evaluate Omnium development timeline benchmarks, derived from thousands of development programs in our archive.

**STEP 5**
The majority of clinical trial cost is related to patient enrolment. Typically, a ballpark cost per patient figure will be applied to estimate cost per trial phase. At Evaluate we use our extensive library of granular trial and per phase cost benchmarks, derived from real world observations.

**STEP 6**
Include costs for submission to regulatory bodies and associated licences.
Manufacturing and COGs

It may not be possible to include this at this stage, however if the manufacturing process is likely to involve products made through a biological process, the cost of manufacture and distribution will be higher than for a small molecule.

Forecast revenue

In general, this is where the majority of the time is spent. Depending on the asset, this may be quite straight-forward, or it may have specific dynamics that need to be considered since they will have a material impact on the forecast.

Regardless of the specialty, there will be some core components that will need to be included within your forecast. Since we are dealing with healthcare assets, the fundamental basis of the forecast should be grounded in patient numbers. If there are no patients, there is no market. Once we get the patient number correct, everything that flows from there is relatively simple to deal with.

Epidemiology – getting the patient foundation correct

In essence, we are seeking to quantify the patient population that would be considered eligible to be treated with the product we are concerned with valuing.

Hopefully the indication will have been identified based upon the clinical development program outlined in Step 1 of the Expenditure section.
Questions to ask next are:

1. Is this an acute (one off) treatment or chronic (on-going)?

2. Should you be considering new / incident patients or prevalence?

3. Do you need to know how long patients live for with the condition? Is this likely to change over the period of the forecast or as a direct result of new therapies or diagnostics entering the market?

4. How easy is it to find data for this condition? Is this widely studied and defined or is it a rare / niche disease?

5. Is this disease a sub-population of a larger condition? Are there factors that could influence this sub-population within that larger condition? (e.g. if you are dealing with a sub-population that develops due to progression of the main disease, if there are new therapies, changes in guidelines, improvements in patient management or even disease prevention, these will all impact the eligible downstream patient population).

There are many factors that can affect your eligible patient population from the epidemiology side. Some diseases are more dynamic than others and it is important to differentiate if your disease is dynamic as this can cause significant disruption to your forecast.

Market dynamics and landscape

Once you have a solid patient foundation to build on, you are ready to consider market dynamics such as:

- Share of the market that you can capture with your asset.
- Current market landscape – who’s treated with what.
- Future market landscape – how is the landscape likely to look by the time the asset launches?

This is undoubtedly one of the most subjective areas of any forecast. Competitive landscape is possibly one of the easiest to find data on in this section.
For estimation of patient share capture, an understanding of unmet need, clinical efficacy and side-effect profile are useful guides. Some consideration to reimbursement can be included at this stage as long as it is explicitly stated, otherwise this section should deal with the clinical demand requirements, in the absence of market access restrictions (which will be included later in the forecast). The rationale for splitting these two factors is that they will require different strategies and should drive different elements of the forecast. The clinical demand is driven by product characteristics whereas market access has a different set of drivers for consideration.

Finally, future market events should be overlaid to the forecast to impact the market. These could be direct competitors that will compete for patient share or adjacent technologies or classes of product that could affect the market dynamics.

Consideration of physician decisions and clinical management algorithms can help add structure and direction to this section of the forecast model. Ideally, any valuation forecast should mirror the clinical decisions that are likely to influence the flow of the patients from diagnosis to receiving your asset. Flexibility of these dynamics over time will allow you to better understand how your product is likely to perform as the market matures.

Other factors to consider in this section are:

1. **Duration of treatment** – is this a driver in your market? How long are patients typically treated for?

2. **Likely switch dynamics** – if a patient starts on a treatment, can they be switched away to a competitor or are they ‘locked in’ to that treatment for a period of time?

3. **Persistence BUT NOT compliance** – similar to duration of treatment, persistence is a measure of how long patients remain on therapy, but is slightly different to duration of treatment in that persistence tends to be a patient driven metric whereas duration on therapy tends to be clinically driven (e.g. a prescribed regimen that is given for a set period of time or until it no longer controls the patients symptoms, whereas persistence tends to be how long a patient persists with taking their therapy before they discontinue, it tends not to be dictated by a clinical response). Compliance generally refers to the alignment between how the medication should be taken (according to the label) versus how it is taken in reality (patients can miss doses or take doses late / early; however, they are still on the treatment).

Once the patients are in the “right place”, we can convert them to volume and revenue outputs.
Conversion of patients to volume and value

In this section we now convert the patients through to volumes or revenue. Depending on the phase of the asset, it may be more straightforward to apply a cost per year of therapy as a straight multiplier to reach the forecast – this tends to be the case for assets in Phase I. If there is more information available regarding the likely patient dosing, then the following conversion factors should be considered:

▷ Dosing frequency & schedule – how often is the therapy given?
▷ Compliance – how patients take the therapy vs. how it should be given in a perfect setting?
▷ Days of treatment per year / in the treatment schedule – generally for chronic treatment this is likely to be 365, but this will vary depending on the asset / indication.

Price can now be applied to the volume unit (or direct as patient cost per year as mentioned previously) to generate a forecast.
Market access and supply constraints

Next, once the “demand” side of the forecast has been determined, we can start to ‘dampen down’ the forecast with a number of assumptions regarding market access. It is unlikely that from the date of marketing authorisation that there will be widespread adoption of a new product. Generally, there is a lag between MAA date and reimbursement, this varies by country but is a significant factor to include in the forecast since it has a material impact on financial calculations such as NPVs.

Where there could be additional supply constraints due to limited manufacturing / shipping or co-dependency on a companion diagnostic which may introduce its own limitations to access (e.g. therapeutic that requires a PET image for diagnosis or patient confirmation ahead of starting treatment may limit market uptake due to infrastructure restrictions), these should be included explicitly within the forecast to show that they have been considered.

Finding a price point

In the same way as patients are critical for the foundation of the forecast, price is similarly critical in converting those patients to revenue outputs.

For early stage assets, there is not likely to be any clinical outcomes data on which to base a value-based calculation (although models can be worked through with sets of assumptions – this can be useful in determining what endpoints clinical trials need to achieve in order to support a given price). Thus, comparator benchmarks can be identified in order to ground the forecast in something more real than just a guess.

The following aspects can help to identify a suitable product as a surrogate for price:

- **Current gold standard in market** – this might be a direct comparison with a drug, or it might be a procedure cost but should give an idea of the cost of treatment of the patient. When considering the gold standard, please also consider any loss of exclusivity that may occur before the new asset launches – if the gold standard goes through LOE ahead of your drug launch, you could find that your price point is radically different to the price you have assumed in the forecast.

- **Similar class or type of product already on the market in a similar or related therapy area** – in some instances, there are no products in the market or products are of unsuitable clinical efficacy to be a meaningful comparison. By looking at similar products in adjacent areas it is possible to pick a suitable benchmark as long as the rationale is reasonable as to why this product or class was picked and how it is similar to the situation you are seeking to value.
Dealing with risk (and probability)

Analysing risk
At this point we should have a workable forecast model that covers key dynamics within the market alongside any areas of ‘risk’. Throughout the process there will undoubtedly have been areas of concern, e.g. there is no data regarding treatment rates in the population or duration of therapy is unknown etc. These ‘unknowns’ are important to pay attention to. They should be documented as areas of potential risk since they are unknown.

It is prudent to run a sensitivity analysis on any forecast model, especially where there are assumptions, in order to understand the potential impact of the unknowns on the forecast outputs. You will quickly find that some unknowns / assumptions have a bigger impact on the forecast than others. Pay more attention to those that have a greater impact as these are the areas of highest risk.

Mitigating risk
List out the key assumptions / areas of risk and see if there is anything that can be done to provide greater insight or reduce the variance of the assumption. This could be simply purchasing some data or a report that gives greater confidence to an area of the forecast.

Areas to pay most attention to will be:

1. **Patients** – making sure the foundation is as accurate and robust as possible.

2. **Share of market** – close estimation of the share of the market you are going to capture with the product.

3. **Competitive / future landscape development.**

4. **Price.**

These are the fundamental drivers of the forecast.
Presenting risk & probability

Risk & probability, while different but linked, are interesting concepts to present since they can be difficult to convey in the context of a forecast.

The typical way of presenting risk is the tornado chart – where an NPV or peak revenue value is taken at “baseline” with a defined set of assumptions, each assumption is then flexed around that baseline value to produce a low and a high revenue / NPV output. These are then presented as + / - in a bar chart format to convey the degree of impact each of these assumptions has on the revenue or NPV value.

In this way, senior management can get a sense of where there is a high degree of risk or lack of information and derive a strategy to address this and reduce the risk or degree of variance in what is known vs. unknown.

Please note that some areas of the forecast will be near impossible to reduce in terms of risk and range since they are dealing with future predictions and thus can not be known. However, this may only be the case with market share. Patients and price will be defined boundaries that can be found, documented and understood.

Probability is slightly harder to convey as it almost deals with the likelihood of the ‘risk event’ happening or being true. Probability is generally reserved for portfolio valuations where a basket of assets is being compared and considered for investment or priority for development acceleration.

Beyond assessment of risks around variability in assumptions built into a forecast, depending on the ultimate end application of the forecast it can also be appropriate to risk adjust revenues for the likelihood of R&D success. At Evaluate we leverage our extensive Evaluate Omnium catalogue of phase, technology, mechanism, and indication-specific probability of technical and regulatory success (PTRS) benchmarks to facilitate this analysis, including product-specific PTRS models.

Of course, this is a more comprehensive list of what should go into an asset valuation; however, it is likely that some of this may be missing in most valuations that you may come across.
Core essentials to pay attention to

As per the fundamentals of forecast drivers, attention should be paid to:

**Patients**
What is the patient number based on? Is it solid and robust? It may not have to be robust enough to go in front of investors, but it is a significant driver of the forecast and should be a solid number on which the forecast is based.

**Price**
What price has been applied? Has this been adapted for country or region? Typically, the USA has a higher price point than Europe due to differences in the pricing environment and how prices are set within the healthcare market. Have LOE events been included?

**Competition and market events**
Have additional market competitors been included in the forecast? If the forecast is worth investing in, it is likely that there will be competitors entering the market in the future, these are likely to impact revenue and any financial metrics calculated from the forecast. Are there any significant changes expected in the market? Changes in guidelines and treatment protocols, diagnostics, vaccines?
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**www.evaluate.com** | **@EvaluatePharma** | **@EvaluateVantage**

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**Evaluate Headquarters**  
Evaluate Ltd.  
11-29 Fashion Street  
London E1 6PX  
United Kingdom  
T +44 (0)20 7377 0800

**Evaluate Americas**  
EvaluatePharma USA Inc.  
60 State Street, Suite 1910  
Boston, MA 02109  
USA  
T +1 617 573 9450

**Evaluate Asia Pacific**  
Evaluate Japan KK  
Holland Hills Mori Tower 2F  
5-11-2 Toranomon, Minato-ku  
Tokyo 105-0001, Japan  
T +81 (0)80 1164 4754