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WHITE PAPER

Risk Benefit Analysis

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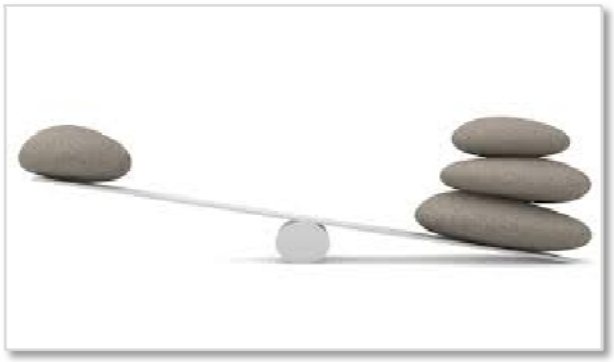
Risk–benefit analysis (RBA) is the comparison of the risk of a situation to its related benefits. This risk benefit analysis happens in every count in the man's day to day life and it activities and carries a great importance.

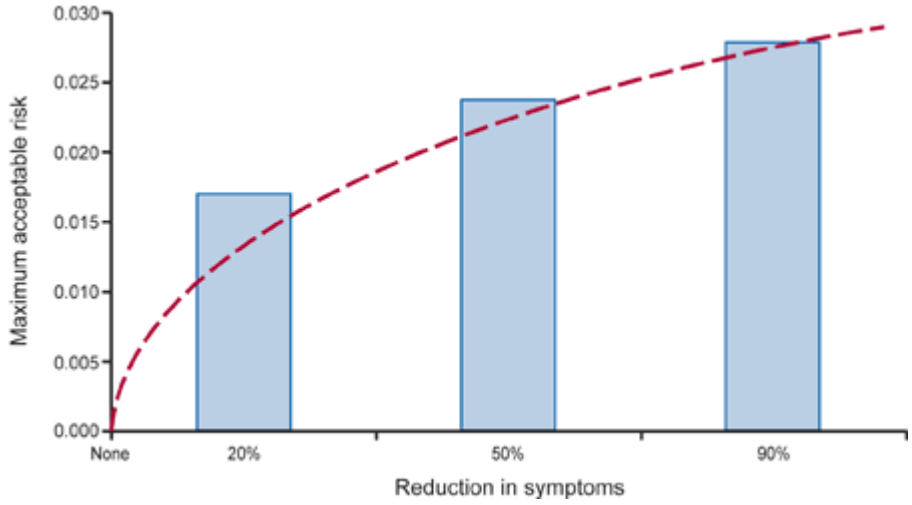
One of the many very key elements where Risk-Benefit analysis should be emphasized is in the area of Medical Treatment. So, the onus of this lies very much on the regulatory authorities to weigh the risk and benefits of that particular drug or device in granting the approval. Also the manufacturing or marketing companies are equally responsible and liable in maintaining and presenting the required data and documentation as per the requirement to the regulatory authorities from time to time.



The Medical and drug regulatory Agency's opinions are based on **balancing** the desired '**benefits**' of a medicine or device against its undesired '**risks**'. Drug or device whose benefits are judged to be greater than its risks will be recommended by the agency for marketing. In contrast, a medicine whose risks outweigh its benefits cannot be recommended for marketing.

As large volume of the generated data should be evaluated and analyzed, comparing and weighing the risks and benefits of the medicine or device is a very complex exercise. And also the data generated is only at a given point in time, this leads to certain uncertainty in assessing the risk benefits.

In the field of pharmaceuticals this risk benefit analysis is a continuous and voluminous procedure that should be carried on till the drug or device exists in the marketing sphere. In performing the RBA one has to look in to the huge available data and analyze the data generated to identify the benefits and risks associated with it. To illustrate, below is an example of maximum acceptable risk estimates for various levels of treatment benefits indicating that patients' risk tolerance increases as benefit levels increase.



In order to come to a conclusion, the available huge volumes of data should be analyzed in a systemic and scientifically strong manner which will give a non short sighted output. As this data will be handled manually there is a possibility of people missing out on a chance of finding a benefit or risk underlying in the accumulated data because of which the manufacturer may lose an opportunity in finding a new therapeutic indication or a potential risk to the users.

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In the earlier days where all the drug regulatory agencies were submitted with data on the safety aspects of the drug in periodically prescribed time durations for updations and it is referred as **Periodic Safety Update Report (PSUR).**

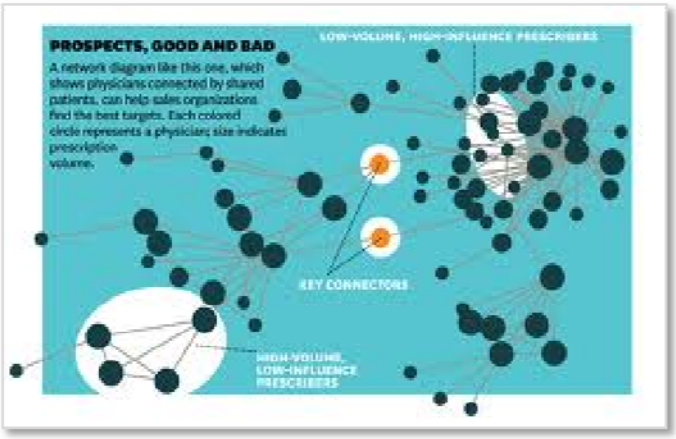
Risk benefit analysis has brought a tremendous makeover in the safety reporting of the drugs. In the present days a new set of periodic safety updates are developed which analyses the risk factor along with the intended benefit caused by the drug and these are coined as **Product Benefit Risk Evaluation Report (PBRER).**

PBRER which also includes risk factor included in the report brings the context of analyzing the risk on lines with the benefit. But in the previous safety updates risk was not analyzed with benefits. It is a time consuming process in company's perspective in compiling these PBRERs as huge amount data should be looked in to it.

PBRER covers all the available data i.e., inclusive of the periodic interval data and as well as the accumulated data for analyzing the risk benefit analysis. PBRER has brought a great change in perception of the risk, as risk is an isolated component in the PSUR updations and with the inception of PBRER risk is considered against the benefit of the drug. New periodic relevant interval data is reviewed in the context of the accumulated data and how it impacts on the integrated benefit-risk assessment. As the accumulated data including the cumulative and interval specific data will be reviewed and analysed, **PBRER is also considered as an analytical document**.

Generally when a drug is sent for a regulatory authority approval, the applicant will be having a limited and somewhat controlled data as it includes data of small population to present it to the approving authority. By and large a far more number of individual patients will be prescribed and they will be exposed to the drug, after approval and once the drug is marketed, thus by giving an opportunity of having a real time data where by analyzing it, the uncovered or undetected indications or adverse effects of the drug can be identified and reported to the regulatory authority. Having real time data in hand the manufacturer will be in a position not to narrow down their ideology rather will be having an advantage of understanding the other areas of effectiveness of the drug by.

PBRER can be a game changer in the thought process of any product, because of its evaluation of the risks and benefits of the drug. Also with risk benefit analysis, the treatment regimen and also the treatment schedules will be revised accordingly by the regulatory authorities.



Conclusion:

For all drugs or devices Risk benefit assessment is vital during their whole life cycle. For each drugs or devices, there is a balance existing between risk and benefit, but the perspective of the situation may vary from regulator, marketing authorisation holder, academic, patient, or prescriber. PBRER lays solid practical foundation which enables the different stake holders to explore and analyze the relationship between risk and benefit, plus review the integration of appropriate strategies within risk management plans.