CLINICAL LEADER

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Why — And How — To Improve Adherence To Treatment In Clinical Trials

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In part one of this series on adherence to treatment, I identified patient nonadherence behavior and its effects on global health and influences in pharmaceutical decision-making. In this follow-up, I will detail the benefits of adherence to treatment, as well as offer immediate ways to leverage current services, tools, and resources to improve patient adherence behavior.

Better Adherence Levels Lead To Lower Costs

Today, there are very few governments that do not have reducing overall healthcare costs and the societal costs of sick days high on their agenda. The criteria to decide whether a drug or medical device is granted market access and included in their reimbursement system may differ per country, but regulators and payers in these countries all start the decision-making process based on data on efficacy, effectiveness, safety, and side effects of a new drug or medical device.

That data comes from clinical trials, which is a very controlled environment. However, it is common knowledge that in many cases the real-world efficacy and effectiveness are much lower, contributing to higher-than-expected overall healthcare costs.

Adherence is essential to the success of any treatment, and low adherence can lead to many negative consequences, including:

- Reduced efficacy, which can lead to an underestimation of the treatment's true efficacy.
- Increased side effects, because the medication may not be able to build up to a therapeutic level in the body.
- Increased risk of complications, which can lead to more expensive and invasive treatments in the future.
- Increased risk of hospitalization and death, because the patient's condition is more likely to worsen and lead to complications.

For all these reasons, it is more favorable to use a drug or medical device with high adherence levels, even if it is more expensive. However, it is important to note that cost is a significant barrier to medication adherence for many patients. Therefore, it is key to consider the cost of the drug or medical device when making treatment decisions.

If a patient is unlikely to be able to afford a drug or medical device that is more expensive but has higher adherence levels, it may be necessary to choose a less expensive alternative, even if it has lower adherence levels. In this case, it is important to develop a plan, together with the patient, to improve adherence. This may involve educating the patient about the importance of adherence, simplifying the medication regimen, providing financial aid, or providing personalized support to help patients adhere to their treatment.

By collaborating with the patient to improve adherence, healthcare providers can help to ensure that the patient is getting the most benefit from their treatment, regardless of the cost of the drug.

Higher, Real-World Adherence Levels, A Deciding USP

Delivering drugs and medical devices with high, real-world adherence levels can be a deciding unique selling proposition (USP) for a pharmaceutical company. This is because adherence is essential to the success of any treatment, and low adherence can lead to a number of negative consequences, as discussed.

In addition, adherence is becoming increasingly important as healthcare systems move toward value-based pricing models. In value-based pricing, providers are paid based on the outcomes of care, rather than the volume of services provided. This means that providers have an incentive to ensure that patients are adherent to their treatment, as this will lead to better outcomes and lower costs.

An example of how to achieve a higher adherence rate is delivering drugs and medical devices accompanied by innovative solutions such

as:

- Digital pill bottles that track when patients take their medications and send reminders to patients if they miss a dose.
- Personalized adherence support programs that provide patients with one-on-one counseling and support to help them stay on track with their treatment. These programs help to provide the right support at the right time and in the right form and can potentially provide valuable feedback to the involved healthcare professionals for individualized follow-up on their patients.

Programs like these are based on:

- Adherence data analytics identify patients who are at risk of low adherence. This allows a pharmaceutical company to design targeted interventions for these patients, such as adherence support programs.
- Patient-centered design that integrates adherence data and involves patients in the design process will help to develop drugs and medical devices to which patients are more likely to adhere.

Pharmaceutical companies that can deliver drugs and medical devices with higher, real-world adherence levels will be well-positioned to succeed in this changing environment.

Adherence Is Also Important To Regulators And Payers

Regulators and payers often rely on adherence levels in both clinical trials and clinical practice when making evidence-based decisions about reimbursements. However, the relative importance of each source of data can vary depending on the specific drug, medical device, or therapy under consideration, as well as the authority in question.

In general, adherence levels in clinical trials are viewed as being more rigorous and reliable than adherence levels in clinical practice. This is because clinical trials are typically conducted under controlled settings with close monitoring of participants. However, it is important to note that adherence levels in clinical trials may not be representative of adherence levels in the real world, where patients may face a variety of barriers to adherence, such as cost, side effects, and complex dosing regimens.

Adherence levels in clinical practice can be measured through a variety of methods, such as pharmacy claims data, EHRs, and patient surveys. While these data sources may not be as rigorous as clinical trial data, they can provide a more realistic picture of how patients are using their medications in the real world.

Regulators and payers often use a combination of data from clinical trials and clinical practice to make decisions about reimbursements. For example, a regulator may require a pharmaceutical company to prove high adherence levels in clinical trials to obtain market approval for a new drug or medical device. However, the payer may also consider adherence levels in clinical practice when deciding whether to reimburse the drug or medical device.

The increasing importance of adherence in reimbursement decisions reflects the growing recognition that adherence is essential for achieving optimal patient outcomes. By considering adherence data when making reimbursement decisions, regulators and payers can help to ensure that patients have access to the medications and medical devices they need to stay healthy and manage their conditions effectively. Regulators and payers are likely to continue to consider adherence data when making decisions about which drugs, medical devices and therapies are most likely to be beneficial to patients.

How To Improve Adherence In Clinical Trials

Given the significant costs of nonadherence in clinical trials, it is important to take steps to improve adherence. There are a number of things that can be done to improve adherence to treatment in clinical trials, such as:

- Educate patients about the importance of adherence and how to follow the trial protocol correctly.
- Simplify the trial protocol and medication regimens.
- Provide personalized adherence support programs that deliver the right support at the right time and in the right form.
- Use digital technology to help patients track their medication intake or medical device usage and receive reminders.
- Monitor adherence to treatment closely and provide feedback to patients.

Today, there are already many providers offering services and solutions that focus on one or more of the above points to improve adherence. The range is wide and runs from simple digital tools sending reminders and intelligent drug containers and medical devices monitoring usage to human behavior-based profiling and segmenting solutions, BEAMER being the latest example of the latter.

By improving adherence to treatment in clinical trials, timelines for clinical trials can become shorter, costs can be reduced, and it will

help to ensure that the results of these trials are accurate and reliable. In the end it will lead to the development of new and better treatments for patients, resulting in lower, more manageable overall healthcare and societal costs.

Why I Am So Passionate About Adherence

When my career took me into the clinical research space of the pharmaceutical industry, I stumbled upon the phenomena of early dropout in clinical trials staying at a steady rate of 25%-30%[1] across all conditions for decades. Early dropout can be seen as an extreme form of nonadherent behavior. When you connect the dots between this, the consequences for clinical trials, and the amount of time and efforts spent on clinical trials, it is obvious that there is an opportunity to do better.

This epiphany led me to my search for a simple, easy-to-use, and effective way to improve patient support and experience to enhance adherence behavior during clinical trials. It resulted in the development of business processes and tools for adherence risk management, based on the Subjective Health Experience model[2] of Prof. Dr. Sjaak Bloem[3]. But it did not end there. The drugs and devices our industry develops will continue to go to market and we will continue to see an even worse adherence situation, eventually affecting all of us. It dawned on me that finding ways to improve adherence is no longer just a professional goal; it is a very personal responsibility as a member of our society. Improving the early dropout rate and the patient experience during clinical trials will have a ripple effect and will eventually make healthcare more sustainable for all of us.

This is why I am so passionate about adherence and why the BEAMER project is so important. If you agree, please support innovative initiatives to improve adherence, such as the BEAMER project, and talk about it with your peers and management. And if you are in the position to do so, actively support the implementation of adherence supporting solutions in your organization.

References:

1. https://nap.nationalacademies.org/catalog/12955/the-prevention-and-treatment-of-missing-data-in-clinical-trials
2. https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-020-05560-4
3. https://www.nyenrode.nl/en/faculty-and-research/people/p/prof.-dr.-sjaak-bloem

About The Author:

Aad R. Liefveld is a member of the BEAMER project team and a member of the advisory board at Link2Trials. He has over 30 years of management experience across multiple industries and is a strong advocate of patient centricity and patient experience. Together with Prof. Dr. Sjaak Bloem (Nyenrode Business University), Aad has developed the Adherence Risk Management Services for Link2Trials to improve patient adherence behavior during clinical trials.

For more information, follow the BEAMER project on LinkedIn.