

Röchling

Patient-Centric Pharmaceutical Packaging Design

Medical



Introduction

Many nations are experiencing a **major demographic shift** in which the over-60 population will soon outweigh younger age groups¹. An aging population has increasing **implications for the healthcare system**, as older adults are at a **greater risk of chronic disease** and often experience challenges with non-adherence to multiple medications.

Medication Non-Adherence Among Older Patients

Medication adherence is already **a serious concern for healthcare providers**. Non-compliance is linked to higher healthcare costs and poorer health outcomes, contributing to nearly **200,000 premature deaths** annually in Europe alone^{2,3}. Adherence to chronic medications is notably low. For older patients, this is often due to **problems with administration** and practical application^{4,5}. Conditions such as arthritis and joint stiffness can **affect the opening of primary pharmaceutical packaging**, especially those with complex opening and closing systems. Cognitive issues can also create **difficulty in taking medication** as prescribed, resulting in errors with potentially dangerous consequences. As healthcare moves towards further self-administration, pharmaceutical packaging must evolve to **meet the needs of a growing patient base**.

Finding Patient-Centric Solutions

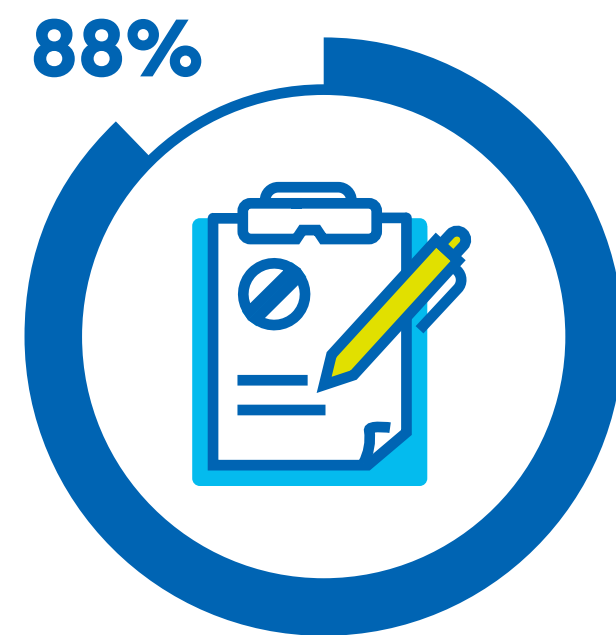
This White Paper will **explore design solutions** and **technological innovations** to respond to the challenges in providing therapeutics and pharmaceuticals to older patients, as well as the potential benefits for other patient populations. It introduces **ergonomic packaging solutions** developed to improve the ease of using tablet containers for patients with physical conditions. Smart packaging systems, including **embedded sensors** and **intelligent technology**, are also showcased, presenting innovative **solutions for greater patient adherence**. The paper additionally addresses further considerations and opportunities for human-factor engineering and patient-driven design.



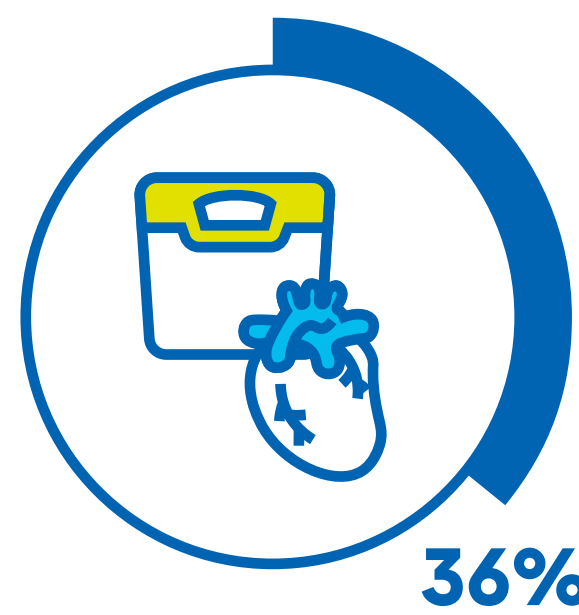
The Challenges of Providing Pharmaceuticals to an Aging Population

The **population is aging at a faster rate**, with the share of people aged 60 years predicted to double from 12% to 22% by 2050⁶. This demographic has a **higher prevalence of chronic health conditions** and **multiple medication usage**. Older patients are also at a higher risk of medication non-adherence due to **challenges with practical application**.

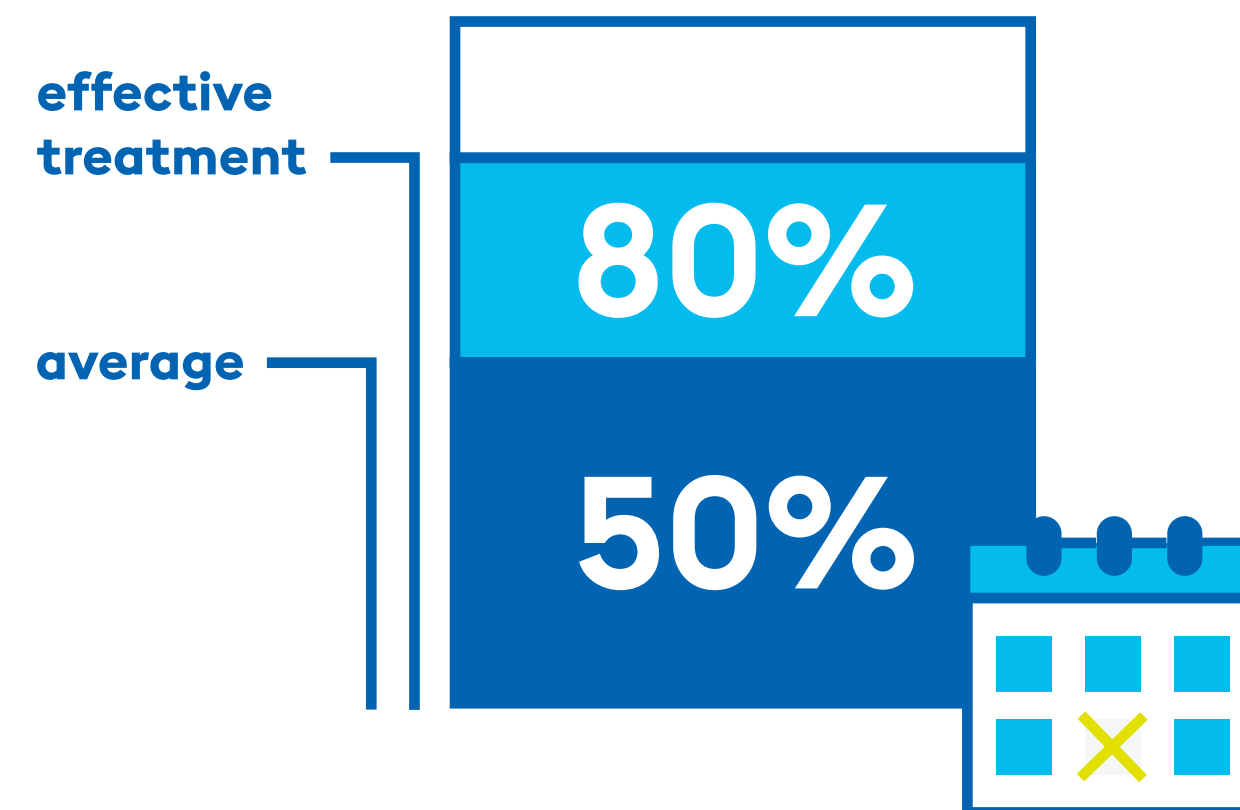
Patient compliance is a global health care concern. According to various studies^{9,10}, **adherence to medications for chronic diseases averages just 50%** - for effective treatment, adherence rates of 80% are typically needed¹¹.



88% of over **65s** use at least one prescription medication⁷.



36% of people aged **65 and over** in the EU have at least two chronic diseases⁸.

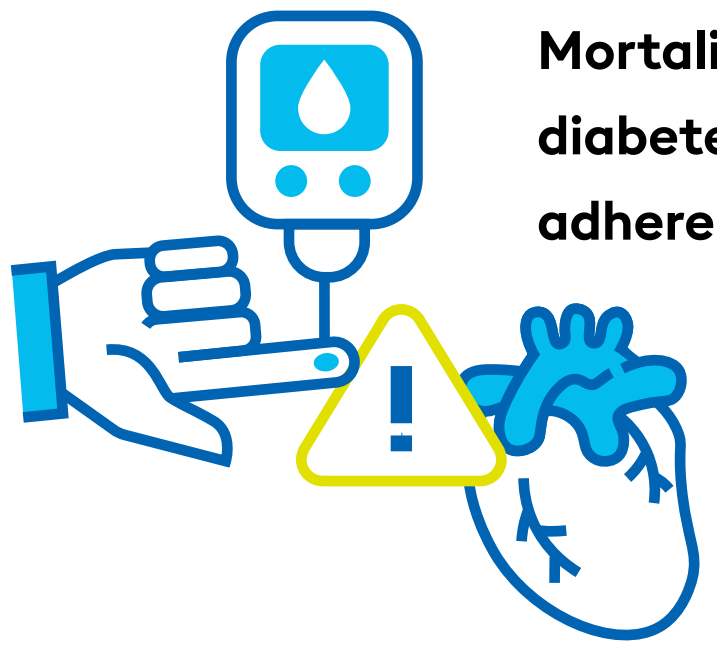




The Impact of Medication Non-Adherence

Medication non-adherence **directly impacts patient outcomes**. It can lead to **treatment failures, higher health care costs, unnecessary hospital admissions, and premature deaths**.

200,000 premature deaths per year in Europe are associated with non-compliance.*

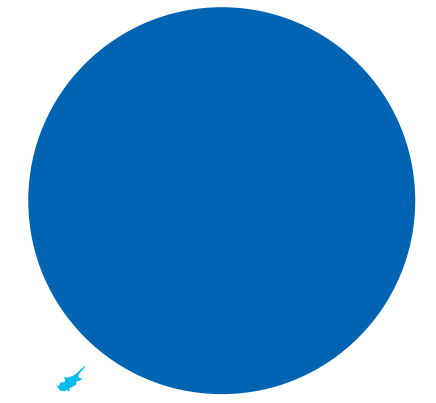


Mortality rates for patients with diabetes and heart disease who don't adhere to their medications are nearly

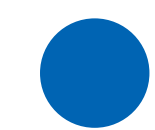
2X as high as those who do¹².

* Estimate

Estimated Cost Per Year of Non-Compliance^{13,14,15}



125 billion EUR



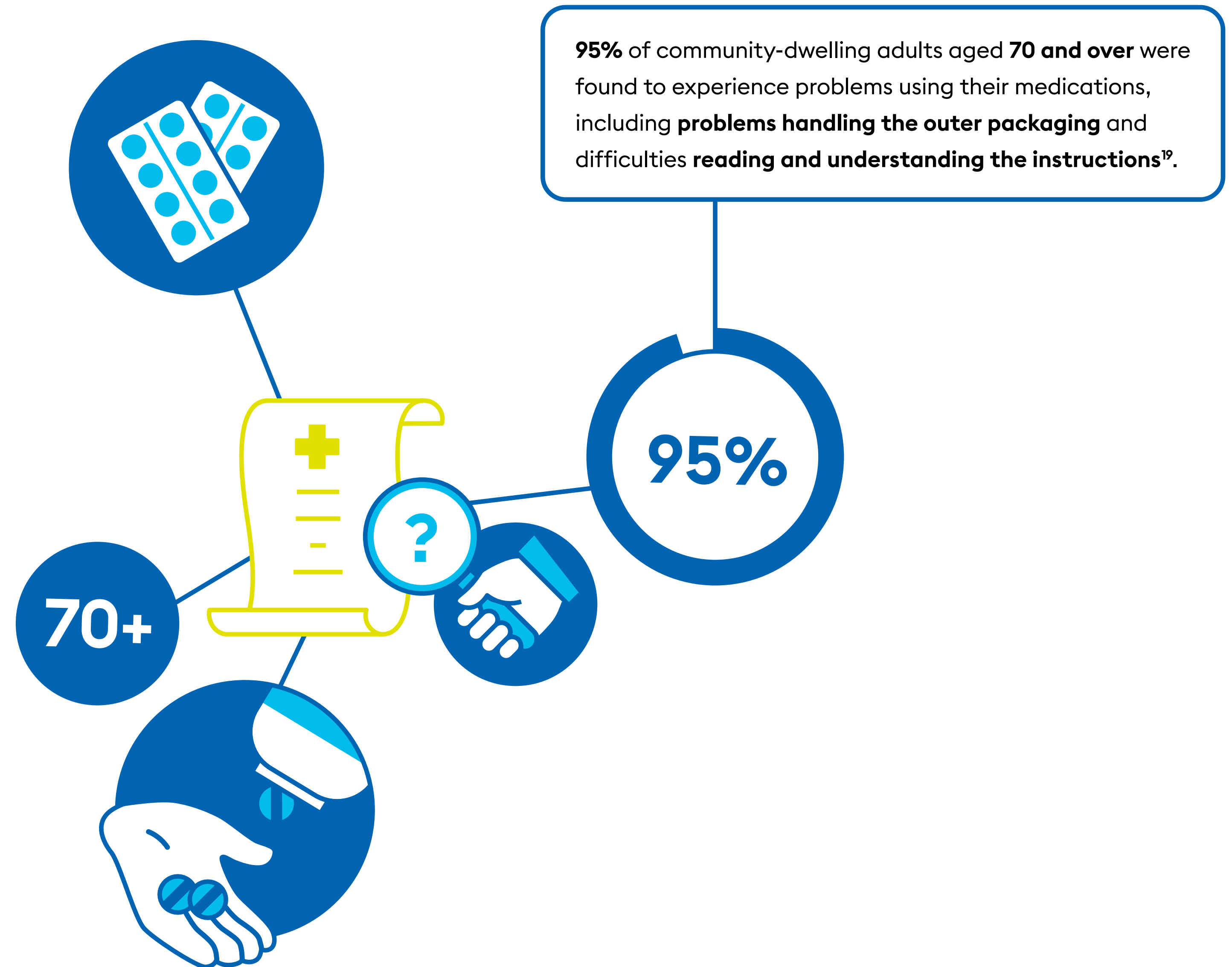
10 billion EUR



500 million GBP

Factors for Non-Adherence

- **Polytherapy increases the risk of non-adherence:** Older patients commonly experience difficulties following complex drug regimens that can lead to errors and adverse drug reactions¹⁶.
- **Motor and cognitive impairments can cause problems with practical application:** Patients affected by conditions such as rheumatoid arthritis can experience physical issues with opening pharmaceutical packaging. Administration difficulties and forgetting to take medications as prescribed are other common reasons for patient errors^{17,18}. Strategies patients use for managing their medications can also lead to incorrect use and negatively impact drug therapy safety.
- **Self-administration is a growing factor for non-adherence:** Capacity constraints and access to health care during the coronavirus (COVID-19) pandemic influenced a further shift towards at-home self-administered care, highlighting a need for more patient-centric innovations in drug delivery.



Patient-Focused Design as a Solution

Studies show that **adherence to therapies** for chronic illness is **far lower than expected**, with as many as **half of patients not using medications as prescribed** to them^{20,21,22,23,24}.

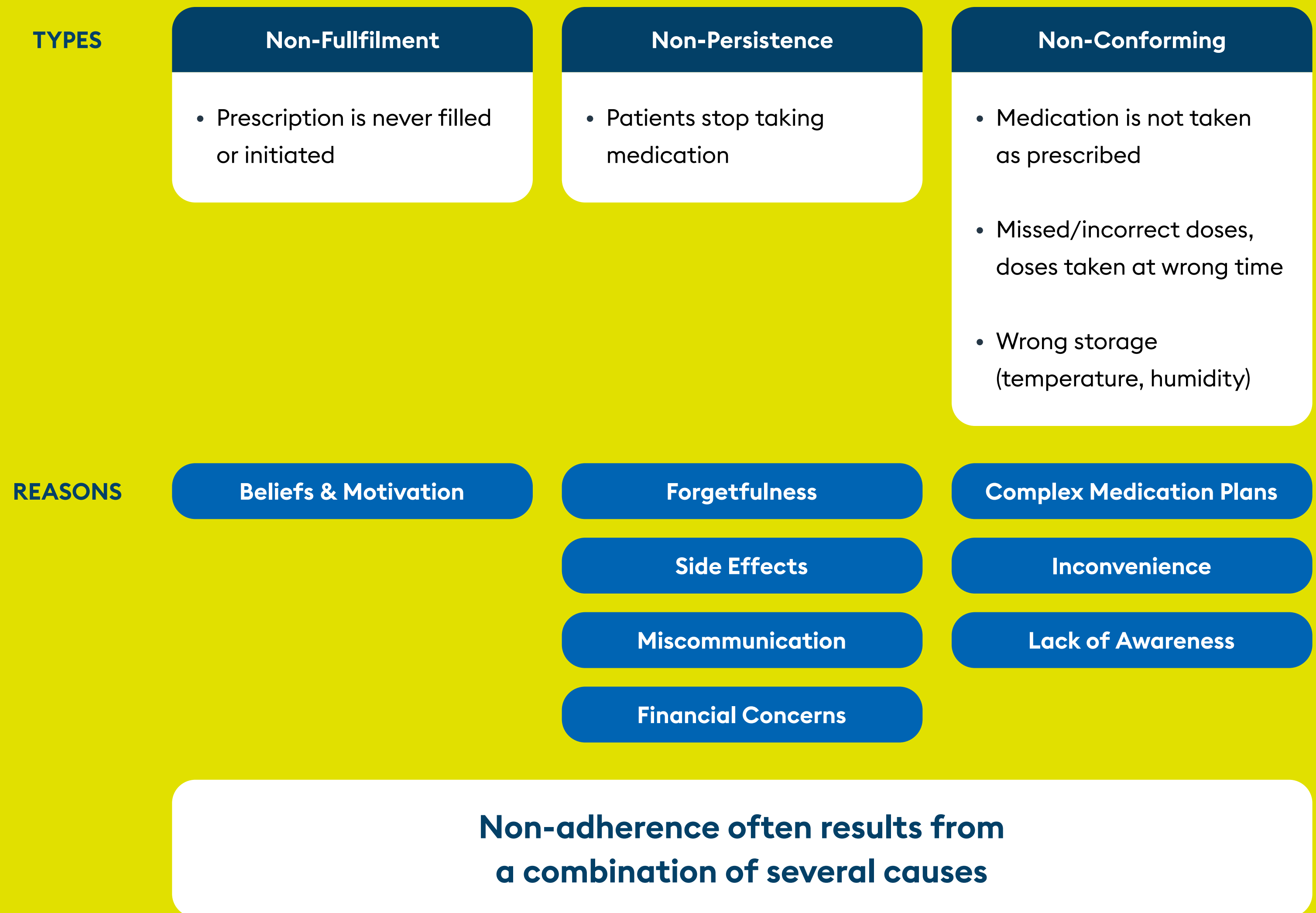
With the problem of **medical non-adherence worsened by packaging-related issues**, medical device manufacturers have the potential to make a **positive impact** on healthcare outcomes **through package design**.

Since patients come from **increasingly older demographics** and factors causing non-adherence can be attributed to a wide array of user issues, the **incorporation of “human factor” engineering** during product design phases is **crucial in improving** optical medical outcomes²⁵.

The Roots of Non-Adherence

Non-adherence among patients is often a **result of a combination of factors** that can be attributed to non-fulfillment, non-persistence and/or non-conforming reasons.

Types of Non-Adherence^{26,27,28}



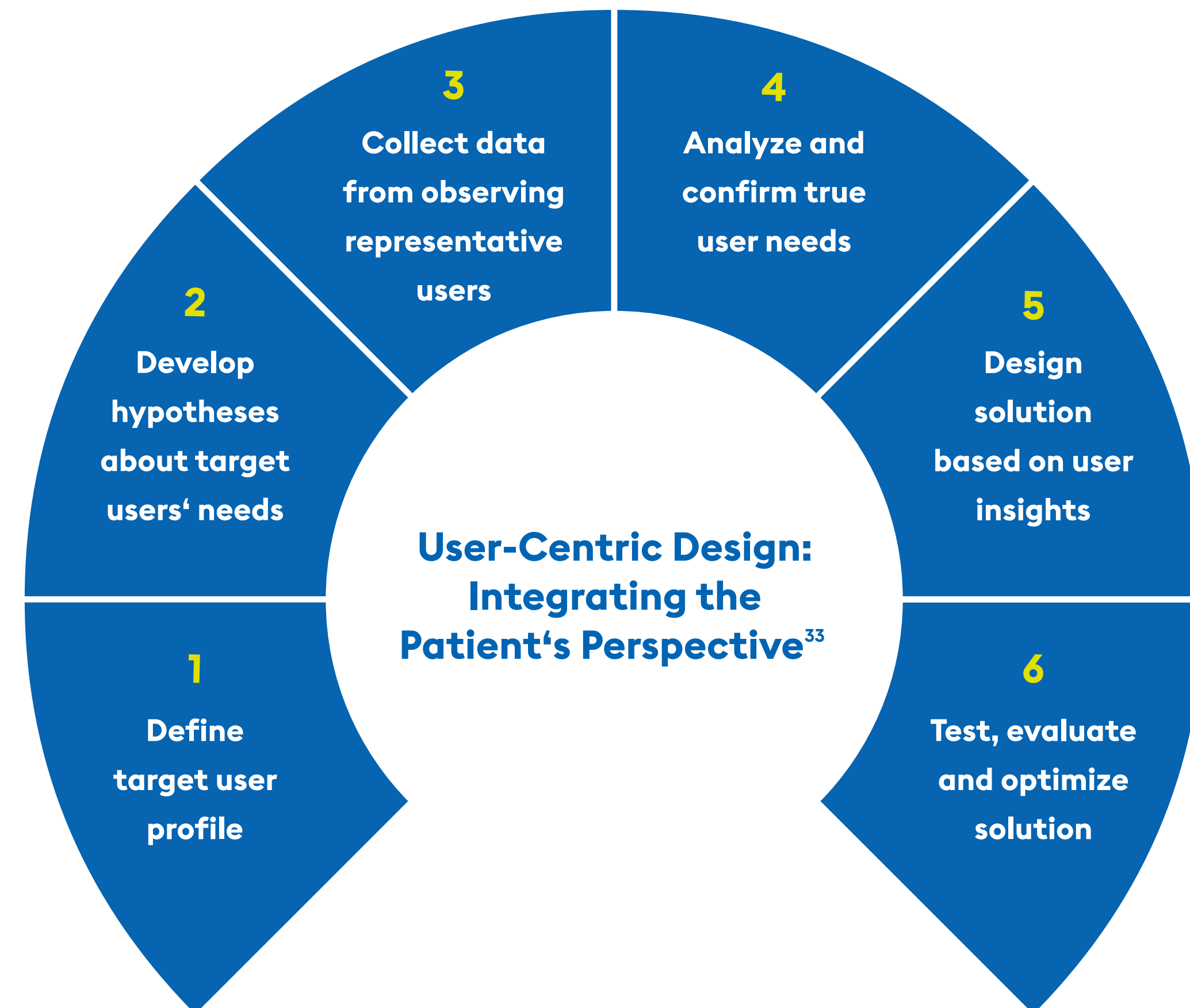
Smartly-Designed Packaging

Recognizing the **challenges faced by patients with motor impairments** struggling to open medical packaging, Röchling Medical collaborated with the Department of Clinical Pharmacology and Pharmacoepidemiology at Heidelberg University Hospital to assess **designs' user-friendliness and manageability**. The study group included **patients with rheumatoid arthritis (RA) and scleroderma**. Those with RA may suffer from joint pain and finger stiffness, leading to **difficulties opening containers**, while scleroderma patients can have puffy skin and reduced blood flow that can cause **severe problems with hand mobility**²⁹.

For this demographic, Röchling Medical cooperated with the Heidelberg University Hospital to **develop tablet containers** that have been **ergonomically optimized** to meet patients' needs. This **patient-centric design process** included affected persons **throughout the testing and development stage**. Accordingly, the smartly-designed packaging solution was developed with the aim of **meeting safety requirements** while **improving ease of use** for patients. Therefore, patients benefit from **reduced effort and pain** when opening containers, which has the **potential to improve adherence**³⁰.

Beyond ergonomically-driven packaging, **patient-centric design** was also core to the development of **Connect-e-Cap®** interactive container caps that can **monitor**

user adherence in real-time³¹, as well as the **Sympfiny®** multiparticulate drug delivery device, **designed to improve incomplete dosing** in children³².

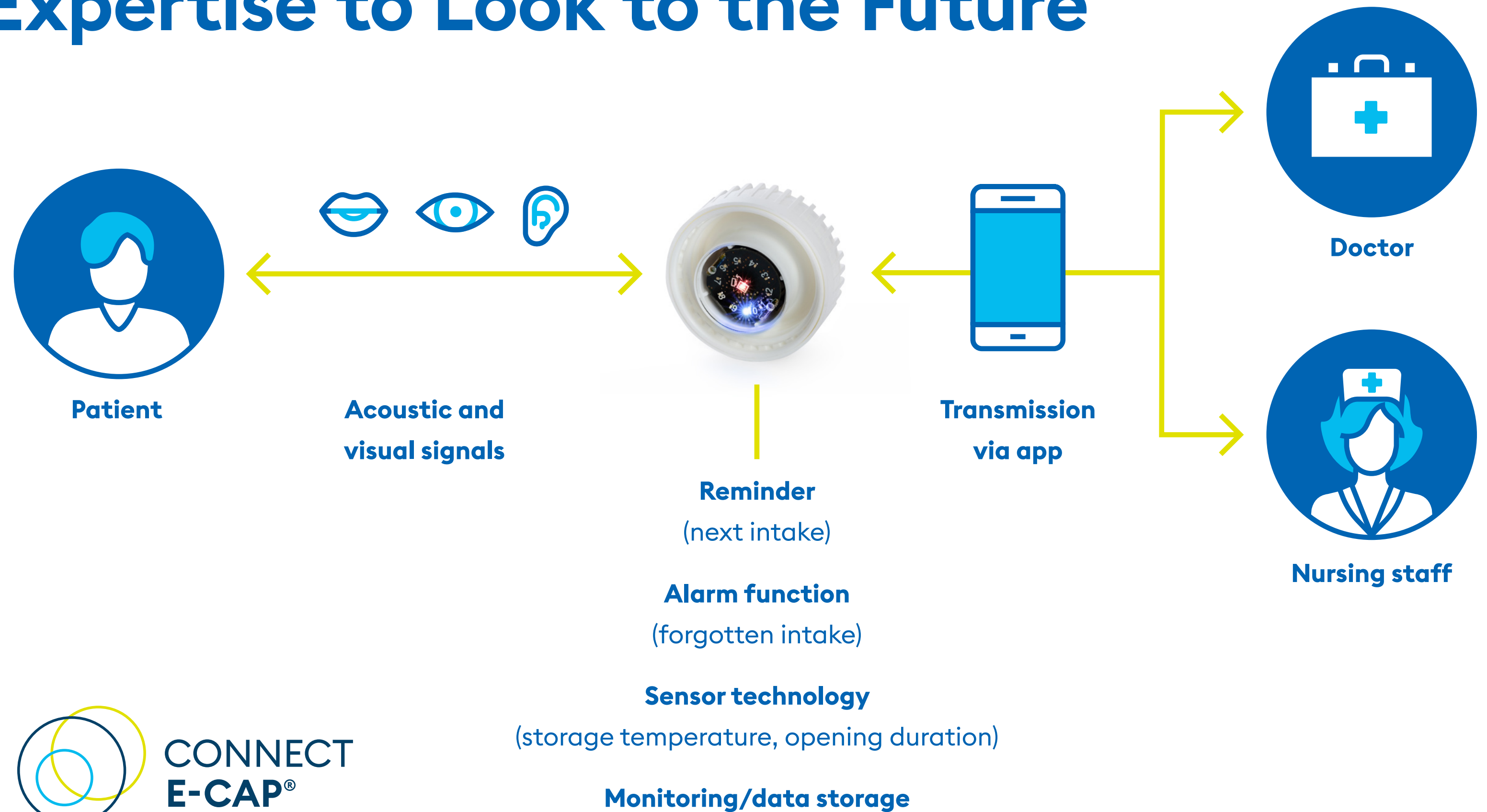


Leveraging Industry Expertise to Look to the Future

Targeting Adherence Issues with Patient-Focused Product Solutions

Successful medical outcomes **depend on patients being both able and willing** to take their medication as prescribed³⁴. Beyond cases of patients facing physical barriers such as RA, non-adherence can also arise on account of users **forgetting to take doses** or **not understanding instructions** for proper use. This is especially relevant as increasing numbers of patients are **taking medications at home** and being treated in **daytime clinics** rather than at acute-care hospitals, meaning that the patients themselves – or their carers – shoulder more **responsibility for administering** their own treatment **without supervision**³⁵.

Engineered through a patient-centric design process, Röchling Medical's **Connect-e-Cap®** intelligent packaging solution, however, can provide **immediate feedback** on the correct use of medication, thereby **addressing many causes of non-adherence**. The Connect-e-Cap® makes this possible by **monitoring the compliance of medication intake**. The **medication schedule**, furthermore, can be tracked through an app.



Key patient challenges are addressed through features including a **reminder function** that reminds patients to take their medication at the required time, as well as **monitoring of correct medication storage** via integrated sensors **tracking temperature and humidity**.

This helps patients **ensure that drugs do not lose effectiveness** through improper storage. Furthermore, via a **smartphone or tablet connection**, the Connect-e-Cap® can **store critical information**, allowing **data to be made available** to the patient or medical staff³⁶.

Further Considerations and Opportunities

Beyond cases in which patient-driven design is based upon the needs of specific groups, such as elderly patients or children, human factor engineering can also be applied to promote the **proper usage of medical devices** in all contexts. The application of **usability engineering** and the implementation of **human-focused design can help** by reducing the need for user manuals and training, as well as **lowering the risk of errors** altogether³⁷.

In the medical device field, however, there is an **ongoing shift** in the **understanding of improper application** of medicines³⁸. Whereas users had previously been considered at fault in the past³⁹, it is increasingly understood that so-called **“human error”** mistakes are **part of a wider failure**⁴⁰, rather than the fault alone of an individual. Accordingly, the European Union regulatory system for medical devices has **replaced the term “user error”** with **“use error”**⁴¹.

For further development in patient-driven design of medical devices, products need to be **tested over extended periods** of time **in real-life settings**. Accordingly, product design needs to be considered as a **long-term process** during which manufacturers, users and other stakeholders collaborate continuously to **generate ongoing improvements**⁴².



Conclusion

The **increasingly older demographic** of medical patients and their corresponding requirements are driving the pharmaceutical industry to take a **user-driven approach** to packaging design.

Patient-centric design is particularly important within the **context of non-adherence** to prescribed medication, an issue that is particularly acute among older patients. Nevertheless, the **growing focus on non-adherence issues** among older populations is also leading manufacturers of pharmaceutical products and packaging to **evaluate means to improve results** among other vulnerable groups.

Medical non-adherence can involve **unfilled prescriptions**, patients **discontinuing their medications** or **incorrect doses**. These issues often result from a number of concurrent factors, including forgetfulness, excessive complexity, and difficulties with administration. This is becoming increasingly relevant as medical care is **more frequently administered at home** or in **day clinics**, meaning that patients themselves are under greater pressure to take medications correctly to **ensure optimal results**.

In the face of these challenges, Röchling Medical has been **incorporating “human factor” interests into its product design** (or product development) processes. In collaboration with Heidelberg University Hospital, we underwent evaluation of **a range of new closure designs** for tablet containers and developed new **smartly-designed packaging** to meet users' needs.

Patients with RA and scleroderma took part in the study of different ergonomic solutions aimed at ensuring **people with motor impairments** would face **fewer hurdles** in accessing their medication and, accordingly, be at a **lower risk of non-adherence**.

Other Röchling Medical products **designed to tackle the issue of non-adherence** are the **Connect-e-Cap®** and the **Sympfiny®** multiparticulate drug delivery device. Similarly engineered through patient-centric approaches, these solutions offer **smart monitoring** functions and **child-friendly dose distribution** accordingly.

Looking to the future, human-focused design is **crucial to ensure high-level medical results** in patients. Since this will involve ongoing testing with patients, product design must correspondingly be regarded as an ongoing process.



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