

A Design Tool and Methodology for Understanding Patients' Capabilities in Medicine Development

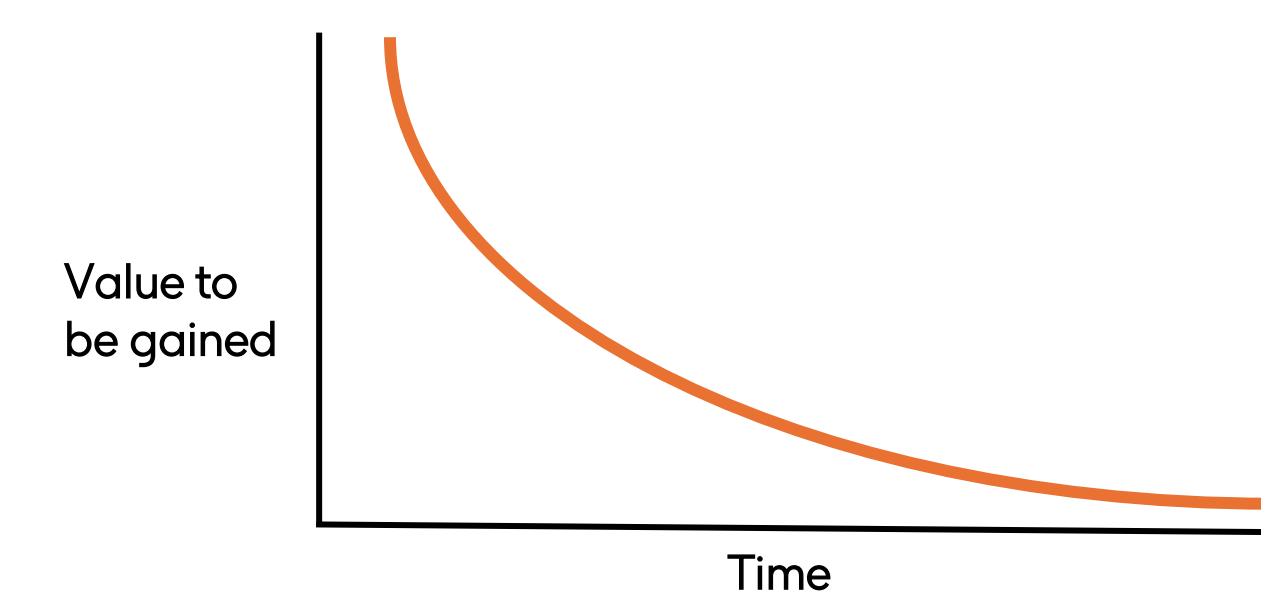
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What are Patient Capabilities?

Patient Capabilities is a term used to describe a spectrum of physical and psychological faculties that enable patients to live and function in their daily lives. Understanding patient capabilities reveals invaluable insights into how patients can interact with Healthcare systems, therapies and medical products. The process of developing patient capabilities profiles provides a key input to the creation of inclusive products and services that are as accessible to as many people as possible. The approach taken at GSK involves primary patient research and data analysis to understand physiological and psychological capabilities of the target users of our medicinal products with the ultimate goal of minimizing exclusion from the use of them.

Key capability areas of focus in the physical domain include Moving, Senses and Diet. In the psychological domain, Thinking and Feeling inform design from an emotional or cognitive standpoint; Living spans a compound breadth of capabilities used in daily tasks such as driving and household care. Acquiring this knowledge through primary research provides input into construction of holistic patient profiles which enables changes in ability that patients experience to be mapped through the course of their health journey.

The risks of failing to consider capabilities early in the research process and the potential impact to success of a new product.



As the research and development process for a new drug or treatment progresses, the ability to influence positively on the patient's experience diminishes after design decisions are locked down and further invested upon. If patient experience is considered midway through development, there are increasing limitations on design freedom to ensure the medication or delivery device is optimised for the best patient experience. Some examples of this are:

- If drug formulation necessitates the medicine to be refrigerated, the constraint this places on patients with very limited mobility (for example, bed-bound) represents an increased burden, or worse, exclusion to access.
- Intercepting the development timeline with actionable insights enables device and technology selection to be steered towards the greatest accessibility for target patient groups.
- Opportunities to influence packaging design and Instructions for Use with a foreknowledge of the specific challenges facing the target patient population can lead to better patient experiences and improved health outcomes through greater adherence.



Our Process

01

Define the Target Patient Population:

Identify the specific patient groups, demographics, geographies and appropriate sample sizes within the patient population of the target disease area.

02

Recruit Patients for the Survey:

Engage third party recruitment specialists to recruit paid volunteers to participate in an online survey consisting of approximately 80 questions across six categories.

03

Patients Complete Survey:

Deploy the online survey to two patient cohorts—remote completion (quantitative) and in-depth interview (qualitative). Completed surveys are submitted and data captured on a server for GSK access.

04

Process the Data:

Raw survey data is rapidly processed on a proprietary GSK automated dashboard for further analysis. The output reveals key signals from the data and highlights common themes to support insight generation.

05

Create Design Signposting:

Through expert analysis of the data by Inclusive Design specialists, design signposting is actioned to translate the findings into meaningful and actionable insights for colleagues making design decisions on behalf of patients.

Moving

Patient and carer self-reported data points relating to physical movement capabilities provides valuable insights. This information can guide decisions on packaging, such as the difficulty of accessing child-resistant casings if strength presents itself to be a common capability loss. Additionally, mobility issues that may hinder patients from obtaining medications or positioning themselves to administer treatments like eye drops or topical applications.

- **General Mobility:** Understanding the general mobility of patients within a specific disease area helps determine, amongst other aspects, appropriate packaging solutions. For instance, if strength is a capability loss, it is necessary to gauge whether patients can open child-resistant bottles.
- **Endurance:** Understanding endurance helps identify patterns in patients' tiredness and sleep quality. Poor sleep quality or excessive tiredness can lead to forgetfulness or confusion, making it challenging for individuals to adhere to their medication schedules, potentially resulting in missed doses or incorrect dosing.
- **Strength and Dexterity:** This aspect has an important role in the evaluation of potential design solutions to ensure that patients are enabled—as far as is practicable—to administer their medication independently without requiring additional assistance.

Senses

Data on senses capability helps in understanding the extent to which accommodation needs to be made for patients with common sensory impairments, such as vision loss. It is essential to ensure that the packaging or instruction text is sufficiently large and clear for patients to read and understand how to use the product.

- **Vision:** Vision plays an essential role in the safe and effective use of medicines, such as reading labels and instructions, distinguishing between medications, measuring doses, and using medical devices. Vision loss can have significant safety implications as well as constituting a significant experiential component of the use of medications. If left inadequately addressed in the design of the treatment, patient confusion and misuse of medication presents an increased risk.
- **Hearing:** The ability to receive and comprehend verbal instructions and communicate with healthcare professionals through hearing is instrumental in most effective healthcare settings. Hearing loss can lead to a sense of isolation and fuel a lack of motivation to engage socially which has broader potential mental and physical health implications that can all be taken into consideration. An assumption of the ability to hear could lead to design of a medical device with audible indicators that locks in a dependence for successful use on a capability the patient may not have, thereby designing in an exclusionary attribute.
- **Smell/Taste/Touch:** Patients may experience a variety of changes to their sense of smell. It can become less sensitive or heightened in sensitivity, which can alter appetite in either direction. Extreme examples may induce a sense of nausea to certain smells or tastes, or lead to changes in appetites to an extent that other health issues are triggered, such as unhealthy weight gain and its associated health risks, or weight loss and malnutrition associated with imbalanced diets. Dietary habits and preferences are of significance to oral medications, where a fasted state may be necessary or conversely, medicine may need to be taken with food or after meals. Thus, understanding the behaviours that are influenced by these sensory capabilities is necessary to determine the suitability of potential treatment regimes to the target patient population.

The sense of **taste** has clear implications for oral medications. Medications with unpleasant tastes can present barriers to adherence, as patients may become sufficiently resistant to routine unpalatable experiences. Changes in taste perception—which can be caused by both medication or medical conditions themselves—might also affect how patients perceive the taste of their medication. With polypharmacy being an unintentional outcome of the treatment for some diseases, the factors affecting patients' sense of taste can become a compound and complex challenge to navigate.

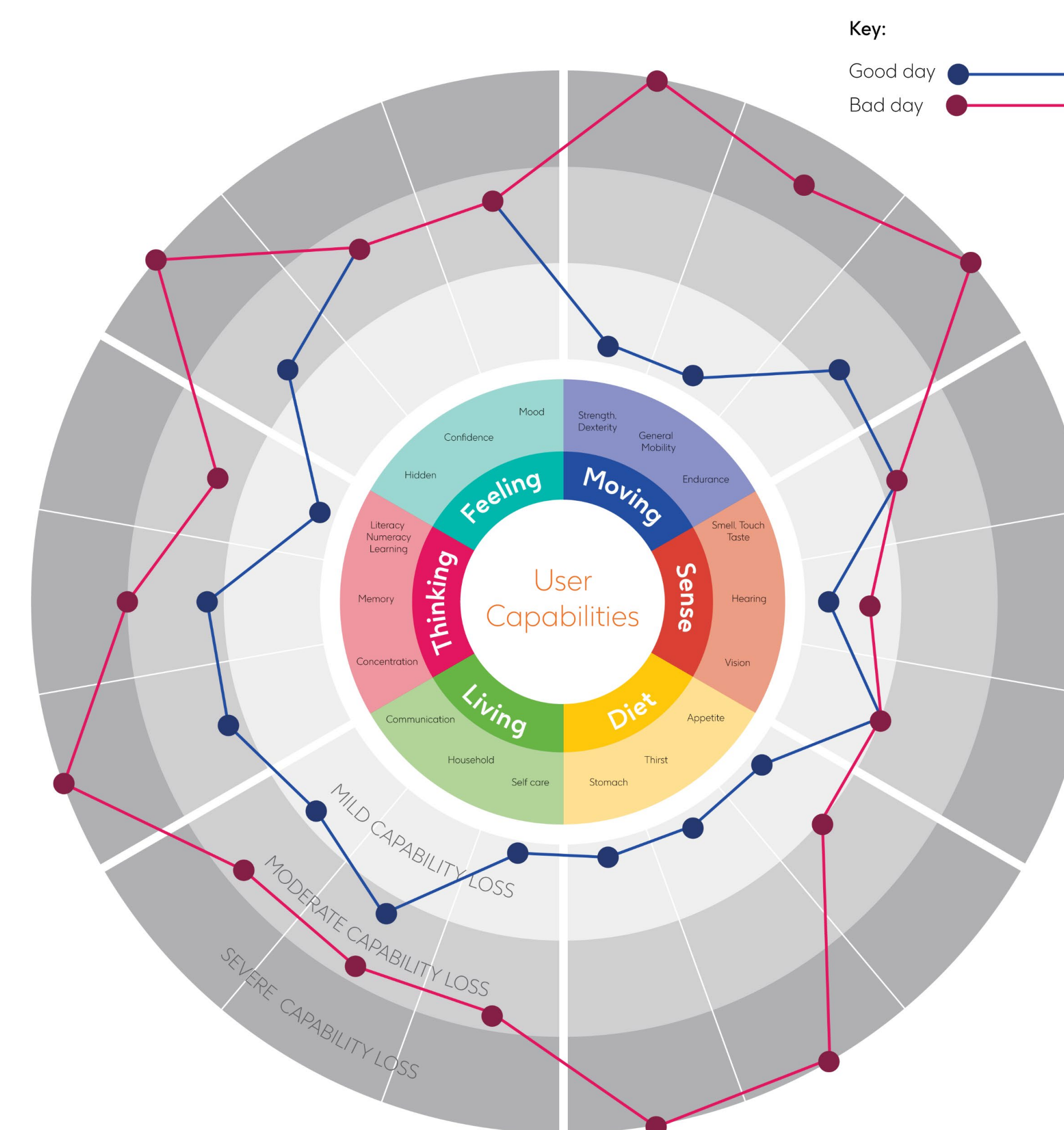
Touch: The tactile sense of touch covers a broad range of sensory experiences including pressure, texture, pain, temperature, and vibrations. As with any other of the senses, these may become sensitised, desensitised or otherwise disrupted in a way that causes discomfort or irritation, such as tingling or itching. Such sensations can lead to secondary issues such as skin damage from scratching, sleep deprivation and self-consciousness. An obvious role of the sense of touch is in the feedback mechanism of handling and manipulating objects. In medicinal products, this relates to handling pills, packaging, leaflets, devices and their associated controls, and is a key part of the intimate experience patients will have of taking their medicine. Bad experiences are a powerful driver for reduced adherence; therefore, a depth of understanding of the design space determined by reduced capability is paramount to creating acceptable use experiences.

Diet

- The dietary habits of patients cannot be considered a capability in its own right, but insight into dietary preferences and behaviours of patients can be shown to have a strong influence on their willingness and or ability to adhere to certain medication regimes. This section considers appetite and thirst and reveals challenges that face patients such as dysphagia, dehydration or polydipsia, each of which drive secondary behaviours that have consequences for the design of non-exclusionary medicinal products.

Six key categories for understanding patients' capabilities in medicine and device development.

The goal was to develop a method of listening to patients in targeted disease areas, aiming to gain a deep understanding of their lived experiences. Validated surveys are a widely recognised research tool for gathering insights from consumers, users, and patients. These surveys offer a systematic approach and enable the collection of larger data sets typically acquired from custom patient research, which typically involves interviewing a small number of patients. Initially, the framework was structured around three categories commonly used in Human Factors research: Physical, Sensory, and Cognitive. An evaluation of validated user surveys revealed the necessity for broader categorisation. As a result, six categories were established, as detailed in the accompanying chart.



Feelings

- Emotional states and feelings that patients experience can significantly impact their ability and willingness to engage with healthcare and treatment. Emotional states such as **anxiety, depression, and stress** may cause patients to be more likely to abandon their treatment, forget doses or take their medication inconsistently, which can affect the treatment's efficacy.
- Feelings can also provide insights into other capabilities, such as impacts on appetite, confidence, relationships and other activities. They can uncover underlying reasons for why certain capabilities may be affected.
- Moreover, feelings of **frustration or embarrassment** related to the medication or the condition it treats can lead to non-adherence. Patients might feel self-conscious about taking medication in public or may be frustrated by the side effects, leading them to skip doses.
- Positive feelings, on the other hand, can enhance adherence. Patients who feel hopeful and supported are more likely to follow their medication regimen diligently. Emotional support from healthcare providers, family, and friends can play a crucial role in fostering these positive feelings.

Thinking

- **Literacy/Numeracy/Learning:** Literacy, numeracy, and learning abilities significantly impact a person's ability to take medication correctly. People with poor literacy may struggle to read and comprehend medication instructions, leading to improper use. Numeracy skills are essential for understanding dosages and timing; those with poor numeracy may find it challenging to measure and administer the correct amount of medication. Learning abilities also play a role in how effectively a patient can manage their own care and medication and puts an onus of responsibility onto the pharmaceutical industry to enable treatment independence, as far as is practicable.
- **Memory:** Memory is a complex area which implicates short-term and long-term memory, as well as prospective memory, all of which have functions in patients' lives that directly and indirectly impact their experience with healthcare and treatments. The propensity for patients to forget things that they have already done—or forget something they need to do in future—has potential to affect almost any aspect of their lives, such as: keeping appointments; recalling if they have taken a previous dose; remembering the preparation steps for a device; or, remembering that they need to remain in a fasted state until they take a medication. Memory capability loss of patients highlights the particular need for development of intuitive user interfaces with sequence independent design and use error-tolerant processes.
- **Concentration:** Concentration loss has many potential causes and associated negative outcomes and illustrates the web of interdependences between many of the capabilities categories. An obvious impact is the inability to follow written or verbal information of any length, highlighting a ubiquitous need for simple information formats to improve the likelihood of safe and effective outcomes. Repeated failure to accomplish a task through lapses in concentration can be linked to frustration and negative experiences, which are common factors in reduction of adherence.

Living

- The Living section provides a broad overview of patients' ability to engage with tasks that require a compound blend of capabilities to achieve common daily living activities. Self-care, the ability to manage personal tasks such as dressing, washing, toileting and driving are all in scope. This data contributes to an understanding of the wider context and the extent to which an individual with any particular condition relies on external support in their daily lives.
- **Household** care includes activities such as food preparation, laundry, and managing personal financial concerns. This evaluation provides context to individual's level of self-sufficiency within their home environment.
- **Communication.** An assessment of an individual's ability to interact with family, friends, and healthcare professionals. This assessment provides insights into their communication skills and identifies any potential impairments in this domain.

When designing a new product or medication, increasing reliance on any specific capability can result in greater exclusion. For instance, a patient who experiences numbness in their hands and feet, making it difficult to handle small pills, open medication bottles, or apply topical treatments. The objective is to design with minimal dependency on patients' capabilities, ensuring inclusivity and accessibility for all users. By adopting a universal design approach, we can create products that cater to a broader audience, ultimately enhancing user experience and promoting equitable access to healthcare solutions.



Contact Details

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