

Agile Market Access

How to create a value dossier in six months

One would expect that routines have emerged from the participants involved in the more than 300 German early benefit assessment procedures, based on AMNOG, which is seen by the authorities as a “learning system”. Instead, uncertainties and ambivalences within the process are rising. The launch of a new product to the market should overall be understood as an interdisciplinary and transfunctional task, performed by existing experts who are interlocked with each other, working together towards a common goal: the preferably sustainable, successful positioning of the new product on the German pharma market. We recommend the establishment of agile working methods to address these issues appropriately and efficiently. Using agile working methods can reduce the period for writing, compiling and completing an AMNOG value dossier by at least one third.



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Dynamic changes during market access

Uncertainties of the approval

According to our experience, the structured and divisional structure bears several uncertainties:

- The approval text – **the label** – is **adapted repeatedly** until a final version seems acceptable for both sides, the pharmaceutical company and the approval authorities (e. g. EMA), sometimes only shortly before the planned market access.
- The preparation of the benefit assessment process, i.e. creation of the dossier for the early benefit assessment, is usually a linear process, which often starts **twelve months prior to the planned launch date**.
- The parties involved in the creation process generally assume stable environmental conditions. However, especially for products with an orphan drug designation, it can be observed that **the “final label” undergoes significant changes** during the dossier preparation process, necessitating in substantial adaptations in the dossier and the herein developed value story.

Overall, these dynamic changes during the market access process result in extensive resource adaptations and consequently in substantial additional expenses.

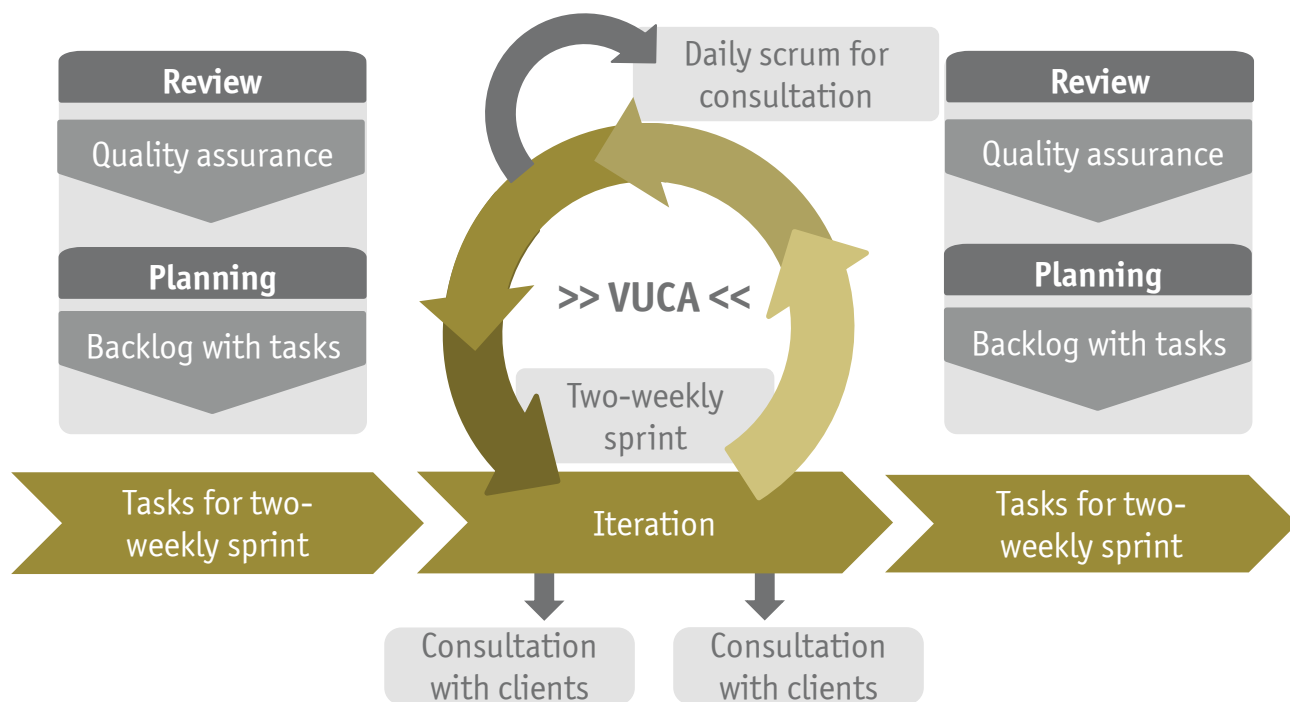


Figure 1: Two-weekly iteration in cycles (sprints)

Multiple Risks

A strongly segmented structure with sequential responsibility bears additional risks:

- The pricing and reimbursement perspective are not sufficiently taken into account during the dossier preparation and the hearing procedure. As a result, **evidence** for the value message need to be stated but cannot be found or **does not exist** in the central document – the benefit assessment dossier – or in the recording of the hearing from the Federal Joint Committee (G-BA).
- The so-called standard of care and thereby appropriate **comparative therapy may change** for indication areas where new drug classifications, that sustainably re-define the treatment paradigm, are introduced to the market (e.g. the indications malignant melanoma and non-small cell lung cancer). Thus, the studies gathered for the justification of the additional benefit now refer to the “wrong” comparator having an influence on the price negotiations.
- The **procedures**, especially the preparation of the dossier, take way too long, **are too inflexible** and the litigation risks are too high.

One can assume that volatility, uncertainty, complexity and ambiguity will strongly continue to become more significant in the setting of innovative drugs. To overcome these “**VUCA-challenges**”, we recommend applying agile working methods, which we have implemented for all our market access projects and which we are utilizing together with our clients very successfully.

New roles

The market access process should be executed **iteratively in parallel workstreams**, specifically the preparation of the dossier, by an interdisciplinary team. This is referred to as so-called scrum project management. The scrum iteration cycles (so called sprints) last for two weeks each und are managed and supported by two functions:

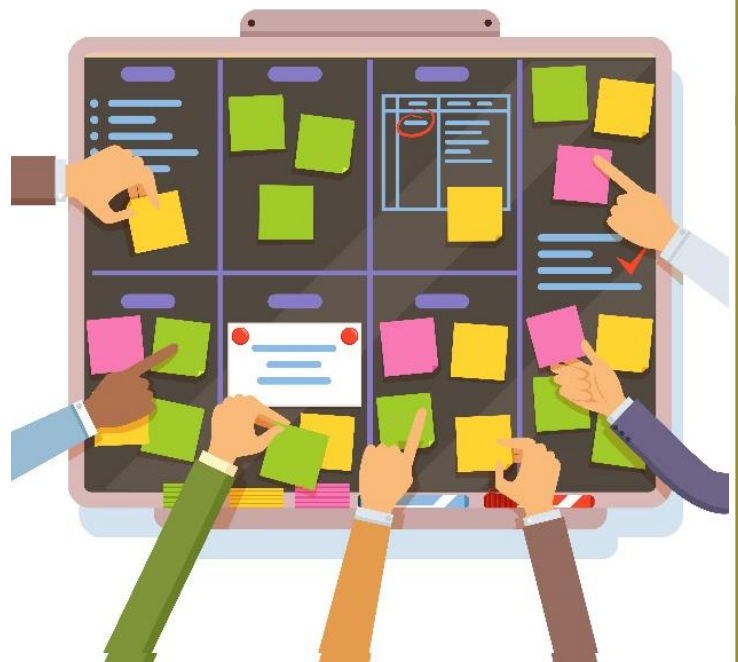
- The scrum master who functions as the master of ceremonies. He works together with the team and takes care of disturbances of the process and **overcomes obstacles**, such as misguided or lack of communication and cooperation or personal conflicts within the team, as well as external disturbances.
- The so-called product owner who represents the client's perspective of the completed product. The product owner's role is to convey the expectations and **translate the requirements precisely** and comprehensibly to the team. She is responsible for the features and the commercial success of the product and therefore for the maximum benefit, e.g. in terms of the dossier for the entire market access process (incl. price negotiations).

At SKC, the product owner is the interface to the client and represents the client's interest towards the team, respectively ensuring that **the client's needs are met at all times**.

Defining goals based on established templates

SCC-Produktvision:		Mit Leitfragen
<p>Ein Satz zur Vision: Wie lässt sich das Charakteristische der Produktvision in einem Satz ausdrücken?</p>	<p>Was sind mögliche Ursachen für das Problem?</p> <ul style="list-style-type: none"> • Welche Problemursachen können mit jetzigem Kenntnisstand benannt werden? • Sind die Problemursachen überhaupt bekannt? 	
<p>Hintergrund und Problem des Nutzers</p> <ul style="list-style-type: none"> • Wer ist der zukünftige Nutzer / die Nutzergruppe? • Welches Problem des Nutzers wird durch das Produkt adressiert? • Wurde die Nutzergruppe zum Problem befragt oder handelt es sich um erste Hypothesen? 	<p>Alleinstellungsmerkmal und Stärken des Produktes</p> <ul style="list-style-type: none"> • Was hebt die Produktvision von anderen Ideen ab? • Gibt es überhaupt vergleichbare Ideen? • Warum ist die vorliegende Produktvision besser als alle anderen? 	
<p>Zielzustand aus der Perspektive des Nutzers</p> <ul style="list-style-type: none"> • Wie sieht der idealzustand aus Sicht der Nutzergruppe aus? • Was muss erfüllt sein, damit das Problem aus Perspektive der Nutzer als behoben gilt? 	<p>Risiken und Chancen des Produktes</p> <ul style="list-style-type: none"> • Welche allgemeinen Chancen / Risiken lassen sich zum gegenwärtigen Zeitpunkt für das Produkt? 	
<p>Erfolgswirkung-messbare Ziele</p> <ul style="list-style-type: none"> • Woran kann der Erfolg des Produktes (messbar) festgemacht werden? 	<p>Stakeholder</p> <ul style="list-style-type: none"> • Wer wäre an Entwicklung und Implementierung des Produktes alles beteiligt bzw. müsste berücksichtigt werden? 	
Verfasser/in:	Datum:	

Achieving goals with a transparent and flexible organisation of tasks.



Tasks are clustered and prioritized to break them down to daily fulfillable achievements.

Figure 2: Agile boards: Requirements and documentation of tasks

Synchronized approach





A fixed rhythm of project workflow is established to achieve maximum transparency among team members:

1. A planning meeting when a **sprint backlog** of tasks is compiled from formal, tactical and strategical requirements for the product/dossier.
2. The two-weekly sprint can start now. Every morning, the team, scrum master and product owner gather for their **15-minute scrum** for reporting about and anticipated barriers.
3. After two weeks, a review is held to **illustrate what has been achieved**, a quality assurance takes place, and outstanding and additional aspects can be added to the backlog.
4. The new planning takes place, and the next two-weekly sprint begins.
5. A retrospective meeting conducted in regular intervals **generates insights of the entire process on a meta level**, for shared learning and to develop ideas for improvement.

Benefits of agile market access

Advantages of agile working methods

The application of agile working methods for the market access process leads to several positive effects:

-  The time for the creation of a benefit dossier can be reduced significantly, **by at least 30 percent** (compared to the standard approach).
-  The **flexibility** is maximized. One can immediately react to unexpected changes in an adequate manner, without significantly intensifying resource allocation.
-  Market access is becoming a **“learning system”** as all team members are participating in the process due to the iteration and barriers can be identified and jointly eliminated.
-  Our clients learn more about the strengths and weaknesses of their organization in the context of a **transparent, intensive and trustworthy dialog** and can use this knowledge for their optimal advancement.

SKC – Partners of trust

Vision and Mission

We at SKC think that every activity in the health care industry should focus on the improvement of the patient's situation.

We are convinced that the best solution for a health care problem can only be found in a competitive landscape, shaped by innovation and empowered by trust.

We believe a better, more effective, efficient and fair health care system is possible due to digital technologies, interdisciplinary networks and highest professional standards.

Pharmaceutical Industry

- Stakeholder and Public Affairs Management
- Market Access, AMNOG and Reimbursement Strategies
- Strategic Pricing

MedTech & Biotechnology

- Market Access for Innovative Medical Devices (National/ International)
- Portfolio Analysis & Management

Statutory Health Insurance

- Digital Agenda Setting
- Health Care Management
- Strategic Organization Development



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