



Introduction

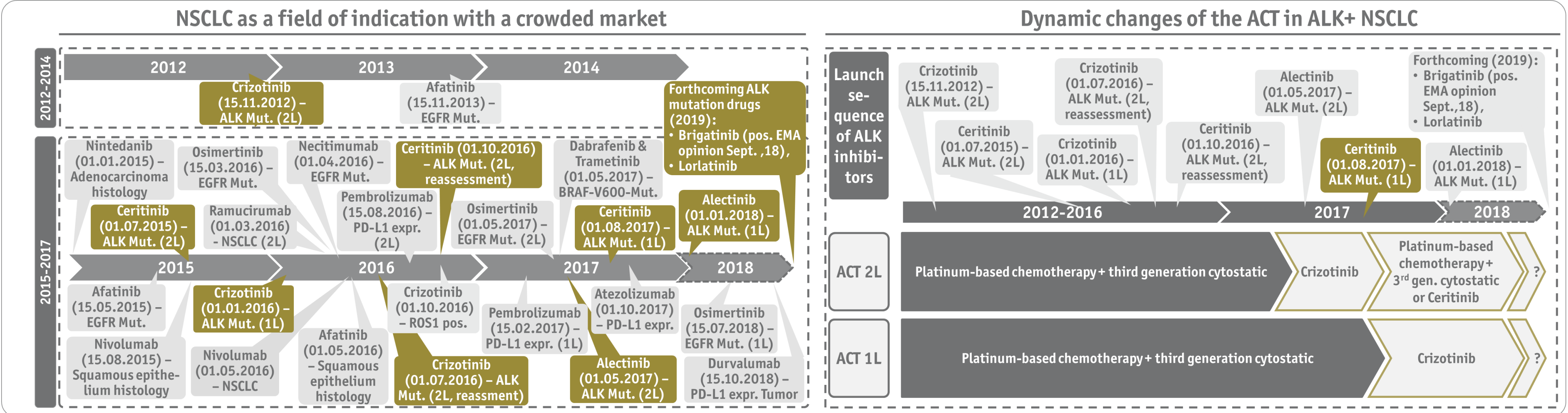
One would expect that routines have emerged from the participants involved in the more than 300 German early benefit assessment procedures, based on AMNOG, which is seen by the authorities as a “learning system”. However, a precise analysis shows, that uncertainties and ambivalences within the process are rising instead. This phenomenon is reasoned in the increased volatility of the market on the one hand and in the high regulatory dynamic on the other hand.

Pharmaceutical companies have reacted to these changes by adapting their organizational and operational structure and by creating competent departments responsible for the benefit assessment process. Nonetheless, a classic, sequential structure of the respective functions can be found in most companies: research and development, medical, regulatory, HEOR/HTA, market access, pricing and reimbursement, and marketing and sales.

Responsibilities often change throughout the twelve months of the “AMNOG procedure”. For instance, it is not uncommon, that the health economic experts, who are also responsible for the dossier preparation and submission and occasionally for the written statement, hand over the responsibility for the process to the pricing and reimbursement team after the oral hearing, which then conducts the negotiations regarding the reimbursement amount with the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband).

The approval process, which is accompanied and managed by regulatory experts – frequently from the European head office – often takes place independently from the market access process. The problems that arise from this traditional approach become evident when the environment changes, especially due to new standards of care, driven by a dynamic clinical discipline e.g. NSCLC (fig.1). 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.

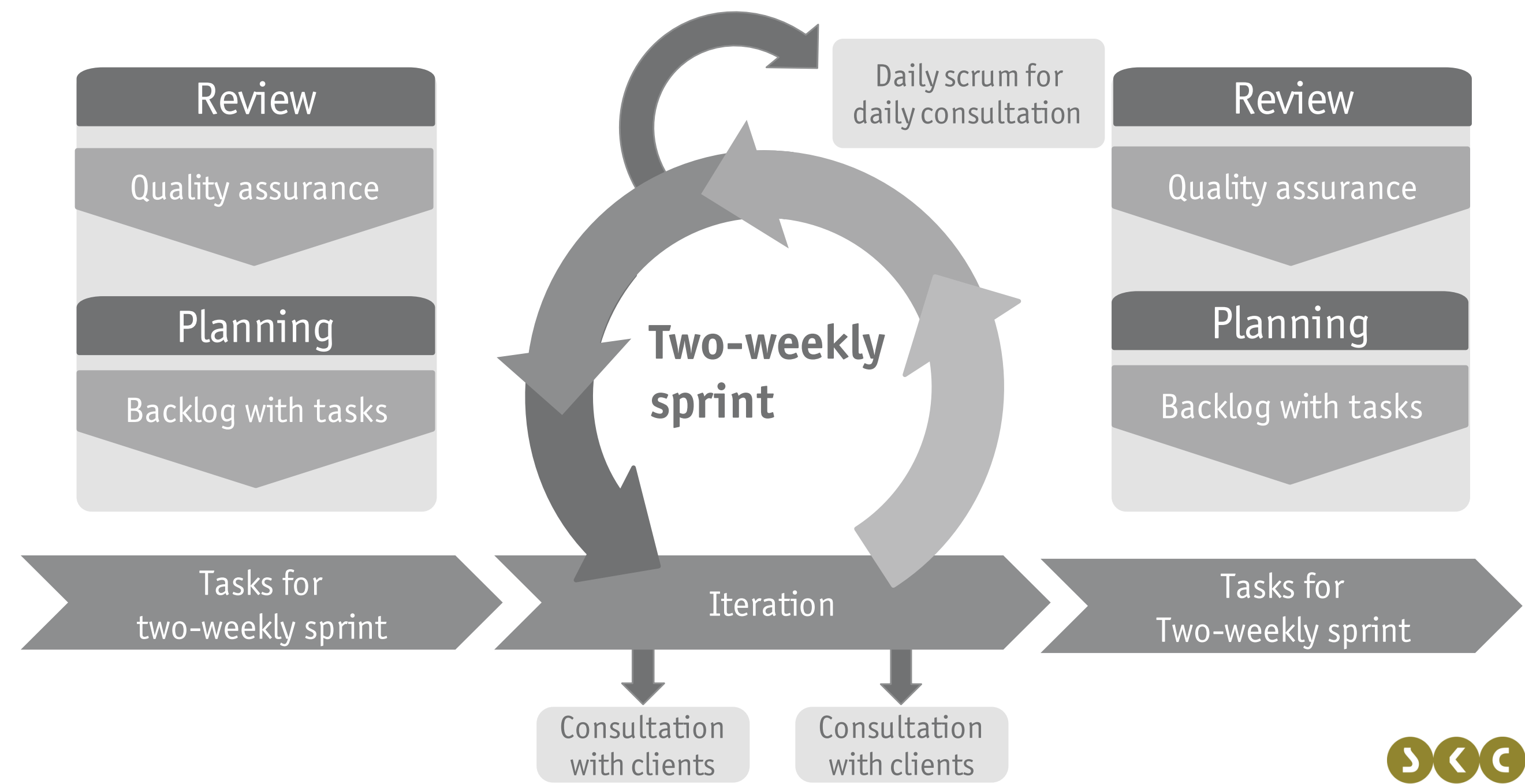


Overall, these dynamic changes during the market access process result in extensive resource adaptations and consequently in substantial additional expenses.

New approach with new tools

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.

Two-weekly iteration in cycles (sprints)



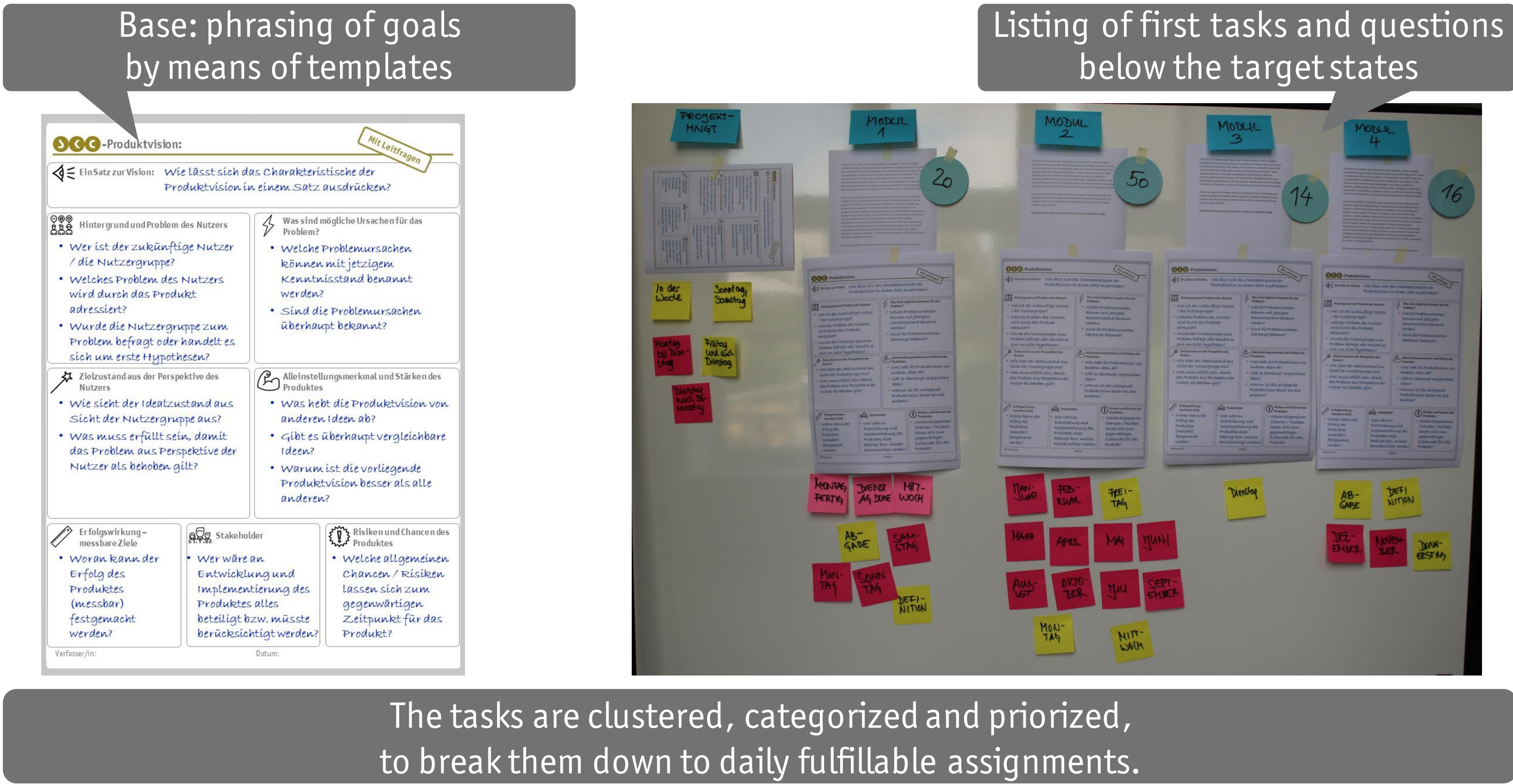
Synchronized approach

A fixed rhythm is established, which starts with a planning meeting when a backlog of tasks is compiled from formal, tactical and strategical requirements for the product/dossier. Once the tasks and the strategic perspective are fully understood by the team, the sprint backlog is stocked, which contains the tasks for the upcoming two weeks. These tasks are broken down to daily fulfillable assignments. The documentation occurs physically on a big Kanban board and simultaneously on a digital Microsoft Teams platform in order to integrate external team members, e.g. the client’s employees.

The two-weekly sprint can start now. Every morning, the team, scrum master and product owner gather for their 15-minute scrum, at which each team member reports about the achievements of the previous day, the daily schedule and former as well as anticipated barriers. The daily scrum achieves maximum transparency, every team member is informed on the status and entire tasks of her peers. 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. In the course of this, the aim, respectively the product vision, is aligned according to the newest insights. Immediately after the review, the new planning takes place, and the next two-weekly sprint begins. A retrospective meeting is conducted in regular intervals with the objective to generate insights of the entire process on a meta level, for shared learning, and to develop ideas for improvement.

New roles

Agile boards: Requirements and documentation of tasks



New roles

The general idea is, that the process should be executed iteratively in parallel workstreams, specifically the preparation of the dossier by an interdisciplinary team, which units all expertise (as described above). 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:

1. The **scrum master** who is responsible for a successful scrum. He works together with the team, yet he is not part of the team. Basically, he functions as the master of ceremonies: he takes care of disorders and overcomes obstacles, such as misguided or lack of communication and cooperation or personal conflicts within the team, as well as external disturbances.
2. The second function beyond the team is the so-called **product owner** who represents the client’s perspective of the completed product, for example the pharmaceutical company. The product owner’s role is to convey the expectations and describe 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 (pharmaceutical company) and represents the client’s interest towards the team, respectively ensuring that the client’s needs are met at all times.

Conclusion

Our experience shows that the application of agile working methods for the market access process leads to several positive effects:

- The absolute time for the creation of a benefit dossier can be reduced significantly, by at least 30 percent (from 9 to 12 months to a maximum of 6 months).
- The flexibility is maximized, so that one can immediately react to unexpected changes in an adequate manner, e.g. in terms of the approval text or the reasonable comparative therapy, without significantly intensifying the 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 weaknesses of their organization in the context of a transparent, intensive and trustworthy dialog, and can use this knowledge for their optimal advancement.

