University of Reading

Research Proposal:
Scientific Advisory Boards: Determinants of their effectiveness

Assignment submitted in partial fulfillment of the requirements for the MSc02/DBA25 program

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"Efficiency is doing things right;
effectiveness is doing the right things. "

--- Peter Drucker

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1. Abstract

For many organizations investing in Research & Development (R&D) the business environment is often very complex in that business decision-making requires an optimal integration of multi-disciplinary scientific information. The quality of science and related decisions can have a tremendous impact on the financial health of a company, and may even determine its future success or failure. In this regard, financial transparency alone may no longer be sufficient to satisfy some investors, and an increased level of transparency in terms of scientific accountability may increasingly be necessary in the future (also see Michaels (2008)). Scientific Advisory Boards (SABs) can be a means to provide scientific expert review and advice, and thus increase scientific accountability. Although the concept of an SAB has a long tradition, neither the determinants of its effectiveness nor the role it could or should play within Corporate Governance practices have been the subjects of any significant scholarly enquiry.

The proposed research aims to identify and investigate the determinants of SAB effectiveness, focusing on the pharmaceutical sector and utilizing the US FDA Advisory Committees (ACs) as a model. A research model was derived from the Corporate Governance literature related to the assessment of BoD effectiveness (Forbes 1999; Levrau 2007) and incorporates potential determinants of SAB effectiveness in terms of its characteristics (diversity and size) and processes (effort norms, debate, and cohesiveness). It is anticipated that results from this research will contribute to evaluating the utility of the proposed model, and also provide an opportunity to highlight the importance of SABs in the broader context of Corporate Governance.

2. Introduction to Proposed Research

Scientific Advisory Boards (SABs) are commonly utilized today across different industrial sectors to facilitate sound business decision-making, particularly in research-intensive companies. SAB deliberations often involve topics related to R&D Strategy in the context of Business Strategy, and, potentially, Risk Management related to R&D investments and its outcome (e.g., novel products and their regulatory approval), while Business Strategy is primarily a typical agenda topic on Board of Directors (BoDs) meetings, and this has received significant attention in scholarly literature particularly after the recent financial crisis. The potential for a crisis in 'company science' exists (McGarity 2008; Michaels 2008) and this can have a significant impact on the financial health of a company. Therefore, the inter-relationship between a company's SAB and its BoD could be considered a relevant topic under Corporate Governance. The roles of an SAB and its inter-relationship with the BoD, and the determinants of its effectiveness have not been the subject of scholarly analysis to date.

For companies to be successful they need to effectively respond to complex business and technical challenges, and realize opportunities within their uncertain and complex environment. Organizations often struggle to realize opportunities and hence struggle to innovate (Conklin 2009). Conklin described this struggle as "Organizational Pain" - the intense need to "communicate and collaborate like never before using systems and tools that were not designed for communication and collaboration". He then argues that a solution is to change the current paradigm – "Age of Science" to "Age of Design", with prediction and control as predominant factors in the former case, and creation and innovation as focal points of interest for the latter. Primary incentives for companies to

invest in innovative technologies are to secure a competitive advantage and future financial growth. Such investments are calculated risks, taken after thorough scientific and regulatory due diligence to ensure sound decisions and creating alternate options to manage uncertainties.

To ensure sound decisions, and also to build credibility (within the investor community) in its science, a company can consult with a panel of independent experts – a task to supplement and support executive and BoD deliberations (also see Manzoni (2011)). In certain situations, an SAB, consisting of external technical and regulatory experts, may be established. Then, ideally, an SAB should also serve in an advisory role to the BoD and provide an independent assessment of the strength of the science and risk posed in the inherent assumptions (also see Hahn (2010)).

Independence of SAB members, similar as for BoD members, would be an important factor impacting on the quality of assessment and advice rendered. Several examples are evident where the scientific credibility of expert panels has been questioned - due to conflicts of interests, biased opinions and skewed memberships (also see the examples outlined by McGarity and Wagner (2008)). The stakes are high, as the following example might highlight. In the pharmaceutical industry, the drug development and approval process is not only long (see appendix, figure 2.1), but also very costly, with up to $ US 1 billion of development costs. At the end of this process, market authorization for a new drug application is either granted or not. A committee of panel experts, in this case an FDA AC, makes recommendations regarding this market authorization. A positive decision can boost a company's stock price, like the recent

approval of Hepatitis C drug Telaprevir[1], which led to a 16% increase of the company's stock price (see appendix, figure 2.2). Similarly, a negative decision can have an opposite impact, as the very recent case of the drug recall of breast cancer drug Avastin shows: Manufacturer Roche is expected to lose US $ 400 million in revenues in 2011[2] alone, not to mention the impact on future revenues for the company (also see the press article in the appendix, figure 2.3).

Consequently, the establishment and management of SAB functions and processes require careful considerations to assure the credibility of the science these panels are dealing with. This is important to provide credible information to guide executive decisions within a company and support the functions of BoDs.

2.1. Aims of research and core research problem statement

The aim of this research is to provide a basis for developing management practices to address the research question - "*What should be key considerations for defining SAB processes and in selecting SAB members to assure an SAB can fulfill its defined purpose?*" A model is proposed to measure fulfillment of purpose, or SAB effectiveness, and the research goal is to evaluate the utility of the proposed model to measure SAB effectiveness. Data will be collected from the US FDA ACs, recognizing that a company-specific SAB may be established and managed in a different way than an FDA AC. The findings of the pilot study (Hahn 2011) have shown that the US FDA AC database provides a wealth of data that can be utilized for research purposes. A survey research methodology will also be utilized to seek input from current and former

[1] Source: http://www.foxbusiness.com/industries/2011/04/28/fda-panel-backs-vertexs-hepatitis-c-drug-telaprevir/ (accessed 26 May 2011)
[2] Source: http://torontostar.morningstar.ca/globalhome/industry/news.asp?articleid=385759 (accessed 6 July 2011)

members of FDA ACs and other SABs on their assessment of the determinants of SAB effectiveness identified in the model.

2.2. Assumptions and Statement of Null Hypothesis

It is recognized that SAB effectiveness, in a broader context, is to provide clear and objective scientific recommendations to an organization (e.g., the US FDA). A recommendation to approve a drug that was recalled at a later point does not necessarily suggest that a FDA AC was ineffective; however, one could argue that an FDA AC was ineffective if it provided its recommendation without adequate efforts to understand and debate the key issues and then synthesize the best possible recommendations. Comparison of how different ACs arrived at their recommendations (approved drugs found to be safe and approved drugs that had to be recalled due to safety issues) should provide an objective means to identify and assess the impact of factors such as diversity, size, efforts, debate, cohesion, etc. on SAB effectiveness.

Over the past decades a number of drugs that were initially approved based on recommendations by an FDA AC, had to be recalled due to safety issues that became apparent after commercialization (for some examples see appendix, table 2.1). In this context, the deliberations of FDA ACs should provide valuable information on how a group of independent experts contribute to debating and synthesizing their recommendations to approve or not approve a new drug. This information should provide data to identify and evaluate key determinants of SAB effectiveness. The process of debating and synthesizing is shown in the figure below, and it is assumed that the two

variables *debate* and *cohesion* are closely linked and contribute to an effective collective decision-making.

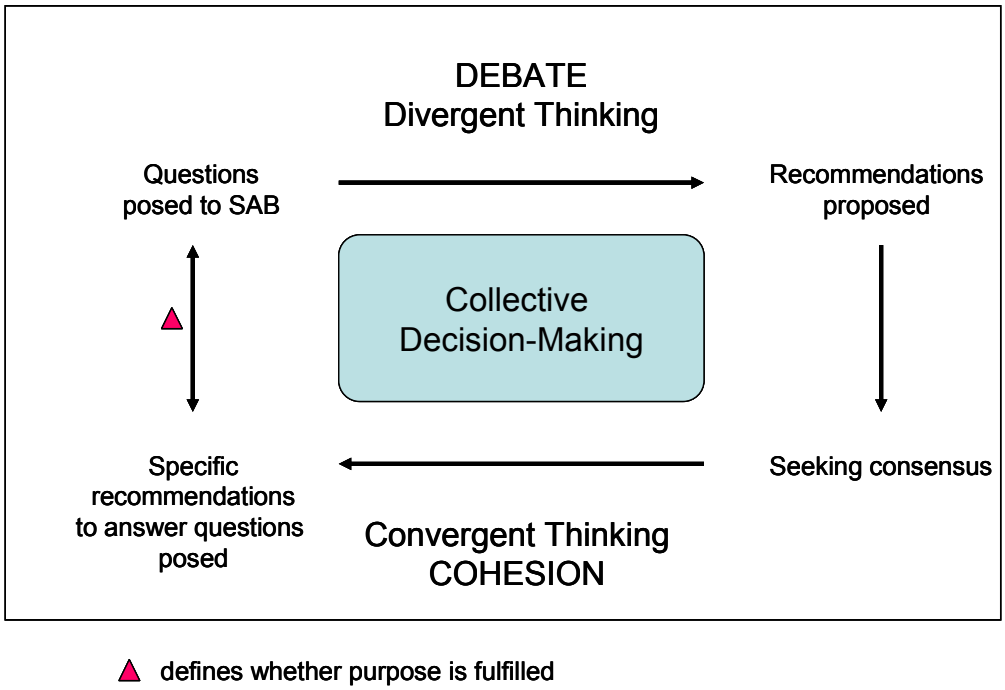

Fig. 2.5 Collective Decision-Making process of an SAB; figure adapted from Pennington (2008)

These and other variables will be embedded in the following research model, which will be used as a framework for the research

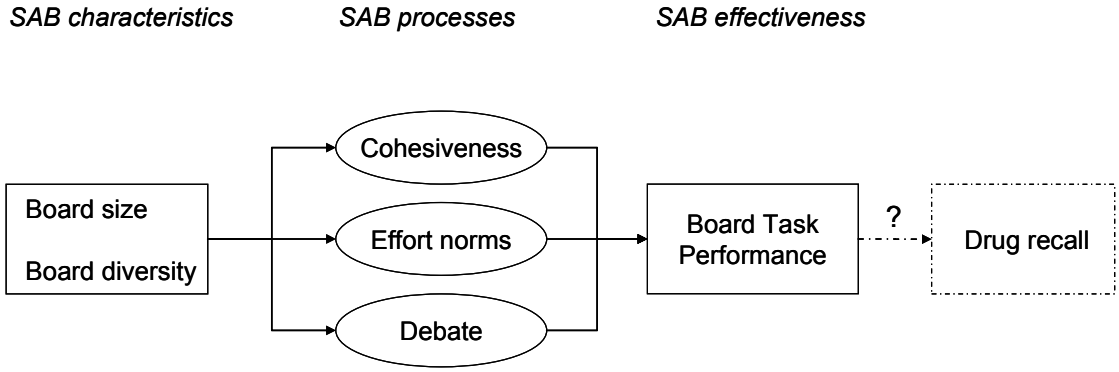

Fig. 2.4 Process-oriented model for SAB effectiveness

The model was derived from the Corporate Governance literature related to the assessment of BoD effectiveness (Forbes 1999; Levrau 2007) and will be further explained in Chapter 4. It is hypothesized that this model can provide an objective means to identify potential determinants of SAB effectiveness in terms of SAB characteristics (diversity and size) and SAB processes (effort norms, debate, and cohesiveness).

The null hypothesis to be tested is that there are no differences among AC diversity, size, effort norms, debate and cohesion measures between FDA ACs that recommended the approval of a drug which was not recalled within a specified period (e.g., 5 years) as compared to FDA ACs that recommended the approval of a drug which had to be recalled within the same specified period. The specified period will be pre-selected and justified based on available data. Rejection of this null hypothesis should suggest a potential utility of the derived model and provide an opportunity to further examine and understand how model determinants are indicative of effectiveness. Not rejecting the null hypothesis may not necessarily suggest that the derived model is not useful or that the FDA practices should be considered as 'best practices' without further considerations.

2.3. Definitions

The definitions of the dependent variable (i.e., SAB effectiveness) and independent as well as control variables will be discussed in chapter 4.

2.4. Limitations

The pilot study (Hahn 2011) helped to identify two major limitations, one related to the proposed technique of data analysis and one related to the generalizability of data. While the former will be eliminated by applying more enhanced data analysis techniques (also see chapter 5), the latter limitation still exists for SABs in a regulatory environment:

Applicability of learning from data derived from the FDA ACs may be limited to product development programs in industrial sectors that are regulated by the FDA. Additional considerations may be necessary for other topics, such as basic research, and other technologies or disciplines that are typically not under FDA regulation. It is also noted that the FDA operates in a very formal setting where extreme attention is paid to avoiding ”conflict of interest” and ensuring (public) transparency; it may be useful to explore to what extent these approaches impact SAB characteristics like board diversity, and how these are relevant for an SAB in an industrial environment.

2.5. Sub-problems

No specific sub-problems are anticipated at this point in time.

3. Literature Review

The Literature Review is structured around the core elements of the proposed research and research model. These are (1) SABs and their core task of providing scientific peer review, (2) the evolution of Corporate Governance and BoD roles and responsibilities to outline parallels to SABs, and (3) elements relevant for the effective functioning of a board, be it a BoD or an SAB.

3.1. SABs and Scientific Peer Review

The history of SABs and scientific peer review

The concept of peer review dates back to the 17th century when the Royal Society implemented a practice of distributing manuscripts to its members for commentary prior to publication in its journal (Shapiro 2006; Bryson 2010). Scientific peer review today mostly relates to the process of publishing in a scientific journal or requesting funding for scientific research. This practice was implemented in the United States in the early 20th century. In subsequent crises like the depression of the 1930s and World War II, advisory committees were established with the goal of tackling social challenges with a science-based approach. While one of the early models of an SAB, the *Depression-era Science Advisory Board*, established in 1956, was not considered a huge success (Hart 1998 as cited in Shapiro (2006)), later SABs proved more successful. The creation of the *Environmental Protection Agency's Science Advisory Board* in 1973 would become a role model in regulatory science (Shapiro 2006). In the decades after World War II, a rise of advisory committees occurred, and in 1972, the Federal Advisory Committee Act (FACA) defined a set of review guidelines. Several presidents, including Reagan, Clinton

and G.W. Bush, contributed to a continuous improvement of these guidelines. In 2004, the US Office of Management and Budget published a final information quality bulletin for peer review (OMB 2004), which was refined in early 2005.

The US was a huge driver in the establishment of scientific peer review. In Europe, the development and practice of peer review did not differ significantly from the US in the period between World War II and the mid 1960s (Lofstedt 2006). In the mid 1990s, distinct differences between practices in US and EU emerged. Since then, institutions in the EU have worked on improving the scientific peer review process. For example, independent scientific committees and risk assessment agencies for both food and medicine were established (Lofstedt 2006). Miller (2006) points out that the peer review process is "far from perfect". In summary, these trends outline the significance and importance of SABs in today's society.

The concept of an SAB today

There are many different categories of advisory boards, at different levels of the organization and with variable levels of independence and accountability. For example, a small start-up company may establish an advisory board consisting of individuals from its CEO's network (e.g., academic mentors, former classmates, etc.). A major corporation with significant investments in R&D may opt to utilize a more formal approach via an SAB, as it seeks the advice of experts in a given area, or multiple disciplines, of science and technology. According to Isaacson, Mitchell, and Starr (1994 as cited by Chok (2009)), SABs are common with small, start-up companies, especially those funded by venture capitalists.

An SAB can be described as a group of managers and researchers from companies, universities and regulatory agencies that come together for formal meetings. These experts generally serve as reviewers of internal research and development efforts, provide strategic advice, and/or guide the company to make good science- and risk-based decisions. Their advice is specifically useful in environments of high technological, regulatory and political uncertainty. An SAB usually has its own budget. Remuneration practices vary across sectors.

The role of an SAB is to provide scientific peer review, thus assuring scientific credibility. Chok (2009) also outlines that the role of an SAB is to transfer and capture knowledge, and stresses that knowledge capture might be used as an IP "hoarding mechanism". For an organization, the existence of an SAB can influence the academic prestige or standing in the scientific community (in both positive and negative ways), and reduce perceived uncertainty for external investors by providing independent, external advice.

Scientific Peer Review principles

Scientific peer review is believed to be essential to promote good science, which will lead to good policy, and ultimately increase legitimacy of decisions. (Guston, 2002 as cited in Patterson (2007)) This ambitious goal might only be achieved if an organization secures high quality throughout the scientific peer review process. Applying key peer review principles is essential to build a solid scientific peer review process. Patterson et al. (2007) cite Patton & Olin (2006) when outlining the following four key areas of responsibilities to define the peer review principles:

1. Independence

"Independence is defined as both distance from the development of the work product and freedom from institutional or ideological bias and conflicts of interest". (…) "Potential conflict of interest needs to be evaluated for each reviewer prior to selection; and a clear and unambiguous conflict of interest policy applied." (Patterson et al., 2007: 1618)

2. Inclusion of appropriate expertise

"The success of a peer involvement hinges on the participation of highly qualified 'peers' - those who are qualified through training and experience to offer scientific opinions on the questions and issues at hand. (…) It is helpful to have the peers come from diverse backgrounds and affiliations (e.g., government, academia, industry, environmental or public interest groups, consulting) to provide a range of scientific perspectives. (…) (I)f there are clear opposing views on key issues, those different views should be included. (…) It also entails that they are prepared to dedicate sufficient time and effort to familiarize themselves with relevant background information." (Patterson et al., 2007: 1618)

3. Transparency

"Transparency refers to a philosophy that encourages open communication about the basis for and nature of the important decisions made during the process of conducting a review, to enable judgment of its credibility. (…) Particularly critical in this context is the basis for selection of the reviewers and sufficiently detailed record of the panel members' deliberations and basis for conclusions and recommendations. (…) Transparency is enhanced with good documentation of the process and results." (Patterson et al., 2007: 1619)

4. Robust Scientific Process

"Robustness is dependent on a number of key factors. Appropriate experts must be involved, the experts must be asked the proper questions to address critical areas, the materials should be complete enough to facilitate a high-quality process, and the results of the peer involvement should be well documented. (…) (I)t is preferable to have a third party, independent of the work product, develop the charge to peer reviewers. The charge asks reviewers focused questions (…) to guide their review. (…) Robustness also involves insuring that the materials are complete and transparent so that the peers can provide meaningful input or opinion. (…) (T)he report should document how the panel reached its conclusions and contain unambiguous recommendations (…)." (Patterson et al., 2007: 1619)

Expert selection process in peer review

A thorough selection and peer review process is essential to ensure that selected experts and consequently their advice will be perceived as credible (also see above), which will ultimately lead to the acceptance of science by the scientific community (Patterson 2007) and other stakeholders. Reputable agencies and societies have defined selection criteria regarding the appointment and participation of scientists in peer review activities. For example, the Society of Toxicology has outlined criteria for appointments and responsibilities both of the appointees and the appointers in its Position Statement (SOT 2008). In principal, the SOT recommends that appointments to SABs should be based on the scientific credentials, demonstrated accomplishments, and professional credibility of the nominee. Other examples include the report by König and Jasanoff (2002) who describe strategies for enhancing the credibility of expert advice.

Why does rigorous scientific review matter?

Evidence suggests (McGarity 2008) that practices exist to manipulate the scientific review process in a way which leads to reduced quality of science, and thus its credibility. Research by McGarity and Wagner (2008) focuses on the interface between science and policy-making/law, particularly related to regulation and litigation aspects in the health and environmental industries; the authors claim that policy-related science is unstable, due to limited oversight and engagement by independent scientists. This might have to be resolved by a restructuring in the area of health and environmental litigation and regulation (McGarity, 2008: 17); potentially by integration into Corporate Governance practices?

3.2. Evolution of Corporate Governance and the BoD role

Corporate Governance history and definitions

Although the term 'Corporate Governance' has gained more popularity only in the past fifteen years, the concept of Corporate Governance itself has a long history. The origins may be traced back to as early as 1776, when Smith (1776) outlined the fundamentals of capitalism. There seems presently no conceptual framework that adequately reflects the reality of Corporate Governance (see Tricker, 2009, as cited in Mallin (2010)). Various disciplines have shaped the evolution of Corporate Governance theory, including economics, finance, accounting, law, management and organizational behavior (Mallin 2010).

Corporate Governance could be described as a mechanism which is essential for business success (also see Mallin (2010)). Good Corporate Governance can help a company to achieve its strategic goals by preventing bad business practices and thus gaining investor confidence. Various definitions exist, for example:

- Mallin (2010) proposes the following features to be part of a Corporate Governance system:
  - Helps to ensure an operating, adequate system of controls within the company
  - Is concerned with the relationship between Senior Management, Board of Directors, shareholders and other stakeholders
  - Aims to ensure that the company is managed in the best interests of all stakeholders
  - Tries to encourage both transparency and accountability to increase investor confidence
- Huse (2007) describes the purpose of a corporation being to establish a long-term, competitive and sustainable advantage over its competitors through value creation.

- Hilb (2005) defines "New Corporate Governance" as a system "by which companies are strategically directed, integratively managed and holistically controlled in an entrepreneurial and ethical way and in a manner appropriate to each particular context."
- Cadbury (1992, as cited in Hilb (2005)) defines Corporate Governance as a system, "by which companies are directed and controlled."

These definitions are based on a number of Corporate Governance theories, of which the most influential ones are mentioned below.

Corporate Governance theories

Often cited main theories having shaped Corporate Governance include *Agency Theory*, *Transaction Cost Economics*, *Stakeholder Theory* and *Stewardship Theory* (also see Mallin (2010)). According to *Agency Theory*, one party, the principal, delegates work to another party, the agent; the main function of the BoD is to monitor. In the context of an organization, much of *Agency Theory* is related to the concept of separation of ownership and control, as described by Berle and Means (1932). The theory of *Transaction Cost Economics* (TCE) is based on *Agency Theory*. TCE views the firm as a governance structure, whereas *Agency Theory* views the firm as a nexus of contracts. Both *Agency Theory* and *TCE* view the BoD as control element. *Stakeholder Theory* provides a contrast to these two theories, by taking into account a wider group of stakeholders rather than focusing on shareholders only. In *Stewardship Theory*, the main role of the BoD is to provide service and advice. While *Agency Theory* is considered as the main theory having affected the development of Corporate Governance in the past, *Stakeholder Theory* is becoming more important moving forward, as more and more stakeholders will (want to) have a say in business matters. One example is the call to

integrate Risk Management into BoD oversight – a topic which concerns not only shareholders but other stakeholders, and last but not least our society.

Roles and responsibilities of the BoD

The BoD represents a core element linking internal stakeholders in the organization (i.e., Senior Management) with external stakeholders, particularly the investors (also see Mallin (2010)). One important means for an organization to be successful in the long-run is to practice good corporate behavior and the BoD plays a critical role in observing whether the corporation lives up to this requirement. Consequently, if the organization fails to meet this requirement, and the BoD fails to point out this misbehavior, long-term success and reputation of the organization will be negatively affected. The Enron fraud scandal illustrated these negative effects (Adams 2010) and was one of many negative examples of Corporate Governance practices; the recent financial crisis has surfaced more missing elements of Corporate Governance, in particular the integration of Risk Management into the system. Often, these negative events and crises have triggered the establishment of Corporate Governance codes.

Corporate Governance codes

To increase transparency and investor confidence, different governance codes and guidelines have been introduced. While differences exist in terms of issuing bodies, legal context or restriction to particular countries or regions, there are a few codes that have been influential from a more global perspective. Table 3.1 (see appendix) highlights the most influential codes and those that might be of relevance for the proposed research.

The BoD tasks

The introduction of these codes has often been paralleled by the introduction of new BoD tasks; for example, Sarbanes-Oxley emphasized the need for financial compliance, leading to the establishment of an audit control task on the BoD. As of today, BoD tasks include monitoring, control and strategic decision-making. One way of classifying BoD tasks is to group them into firm-external, firm-internal and strategic tasks (Huse 2007). In this context, Huse describes the following six main board tasks:

	Firm-external perspective (control tasks)	***Firm-internal perspective (service tasks)***
External focus	Board output control tasks	Board networking tasks
Internal focus	Board internal control tasks	Board advisory tasks
Decision/strategy focus	Board decision control tasks	Board collaboration and mentoring tasks

Table 3.2 Overview of BoD tasks according to Huse (2007)

These different board tasks should be carried out diligently, and thus it is critical for an organization to establish a well-functioning BoD, for which several elements are necessary.

3.3. Elements relevant for the functioning of a board

Board structure and diversity

A BoD may be structured in single tier or two tier forms. In a dual structure, one board consists of the executive management, while the other board is the supervisory board (also see Mallin (2010)). The BoD may create sub-committees (e.g., audit, remuneration, nomination, risk or ethics committees) to delegate its duties. Adams et al.

(2010) point out that, in recent years, regulatory requirements and pressure by external stakeholders have led to an increased number of independent, or outside, directors, to increase objectivity and independence of BoD decision-making. This change in composition might also be reflected in a more diverse board. Although board diversity per se has become an important topic for scholarly enquiry (Hilb 2005; Hilb 2007; Mallin 2010), it is so far rather limited to diversity in terms of gender or nationality (Milliken & Martins,1996; Williams & O'Reilly, 1998; as cited in van Knippenberg et al, (2004)). A topic which warrants further exploration is diversity in terms of transdisciplinary skills, which are of particular interest in organizations dealing with complex business problems and which may consult scientific experts to gain additional advice to solve those problems. While exploring this topic further, the potential downsides of diversity have to be kept in mind as well; for example, Huse (2007) suggests that more diverse boards are more likely to experience coordination and communication difficulties than homogeneous boards, which is particularly due to the fact that no common language exists among these members. Possible consequences are more time-consuming meetings, and less cohesiveness among board members. (Huse 2007)

Board member characteristics and roles

Board members should bring necessary expertise to fulfill various tasks. There are similarities in the tasks a BoD carries out and those that an SAB performs. For example, while control tasks are the responsibility of a BoD, one can argue that service tasks may also be executed by an SAB, whose duty is to provide service and advice related to strategy, but not to make any strategic decision. Parallels in service tasks between a BoD and an SAB are described in the table below:

Service Task	*In the context of a BoD*	*In the context of an SAB*
Networking	- on behalf of internal stakeholders - involve networking, lobbying and legitimacy tasks	- on behalf of internal stakeholders - involve networking, lobbying and legitimacy tasks
Advisory	- Board members may be **consultants to the management** - Board members provide various kinds of knowledge and competencies	- Board members act in an **advisory capacity to the management** - Board members provide various kinds of knowledge and competencies
Collaboration and mentoring	- Board members are expected to **collaborate with management in shaping the content, context and conduct of strategy**	- Board members are expected to **collaborate with management in advising on content and context of strategy**

Table 3.3 Service tasks performed by Board of Directors (based on Huse (2007)) in contrast with those performed by a Scientific Advisory Board

Cross-disciplinary collaboration and collective decision-making

One of the key tasks both an SAB and a BoD need to fulfill is to make effective collective decisions. To effectively manage this decision-making process a facilitator is required who is capable of "orchestrating effective environments and interactions" (Pennington, 2008:2). Pennington (2008) points out that effective, collaborative problem solving remains elusive (Rhoten, 2003, as cited in Pennington, 2008), despite the fact that the need for integrated science has been recognized for quite some time (Di Castri, 2000, Kates et al., 2001, Kostoff, 2002, Cash et al, 2003, Rayner, 2006, Welp et al., 2006; as cited in Pennington, 2008).

Selecting Board members

Due to the similarities in task execution, the process of selecting members for an SAB may be very similar to the process of selecting directors for a BoD. When a firm

appoints its Board, member characteristics (like competence, knowledge, qualifications and abilities), compensation, composition and diversity are important factors to be considered. Compensation is often considered a key motivating factor. From the perspective of the future Board members, however, other factors also play an important role in influencing their motivation. These factors include ownership, desire for power, the possibility of gaining influence, prestige, the potential for learning, increased possibilities in the labor market and the ability to develop networks (Huse 2007). To understand the factors influencing the decision-making process of individuals to join a group of experts, a thorough analysis of the existing literature on motivation and other behavioral aspects is warranted, particularly as these factors might influence the later efforts and communication traits (e.g., willingness to debate) these members show on the board.

Motivations and resignations

While characteristics of individuals and factors influencing their environment play an important role in accessing board positions, the biggest hurdle will be an individual's willingness to join a board. While Dewally & Peck (2010) emphasize the motives and circumstances surrounding directors' resignations from board positions, Adams et al. (2010) focus on the factors influencing an individual's motivation to accept a board position. Dewally & Peck (2010) describe the preservation of reputation capital and business relationships as one of the strongest incentives for outside directors to accept or resign from a Board position. Their findings are based on evaluating a non-random sample of 69 director resignations for 49 separate firms. Also Adams, Hermalin and Weisbach (2010) consider the concept of reputation capital when they investigate the role

of BoDs. They find that direct compensation and reputational concerns are key factors driving motivation, and point to a lack of clear definitive predictions in much of the related general theory, which makes it difficult to model governance issues.

Developing a behavioral theory of Boards

Another area which has received more attention recently is the integration of behavioral theory into CG research. While earlier CG studies were mostly focused on economic performance aspects related to a BoD, recent research by Levrau and Van den Berghe (2007) suggests that behavioral research may help to explain the difference between successful boards and board failures. They present a new model for board effectiveness, including elements like board size, diversity or debate. Also, van Ees Gabrielsson and Huse (2009) point out that it is important to incorporate the study of behavioral theory into Corporate Governance research.

3.4. Summary of the Literature Review

In summary, three major areas are of relevance for the proposed research: (1) Scientific Peer Review and the SAB as tool to carry out this review, (2) Corporate Governance, and the role of the Board of Directors and (3) elements relevant for the effective functioning of a board or team and thus contributing to effective decision-making.

Scientific Peer Review has a long tradition and has received more and more attention in business decision-making, as science aspects are increasingly intermingled with strategic decisions related to the development of new products or technologies (also see Michaels (2008)). The task of a BoD today is to control business decisions, in order

to make sure a firm acts in an accountable manner so that interests of shareholders and other stakeholders can be secured. This and other BoD tasks are regulated in Corporate Governance policies, where SAB tasks have not yet been integrated to date. The anticipated increased overlap of science and business however might require that scientific peer review practices will be integrated into CG practices.

To provide effective and good quality control and advice to an organization, both BoD and SAB members should fulfill certain criteria and bring necessary skills. This relates to technical or functional knowledge on the one hand, and individual and personal skills on the other hand. This Literature Review addresses some of these aspects, yet further research to provide an even deeper grounding in literature is warranted.

3.5. Areas for further research

Further research might include the areas of team science (also see Stokols et al. (2006)), or cross-disciplinary collaboration (Pennington (2008); Rosenfield, 1992, as cited in Stokols et al, 2006). Also, as outlined by Adams et al. (2010), the board member selection process, and in particular the role that social networks play within this process, remains an area profitable for future research. Furthermore, the costs and benefits of diversity will have to be studied in more detail, as outlined by Manzoni et al. (2011). Other suggestions for further research are provided in chapter 6 of this paper.

4. Research Model

To address the research question "*What should be key considerations for defining SAB processes and in selecting SAB members to assure an SAB can fulfill its defined purpose?*" a research model based on existing models will be developed and utilized. In order for an SAB to fulfill its purpose, specific aspects related to its characteristics and processes need to be given. It is assumed that an SAB is effective if the purpose is fulfilled, i.e., if no drug has to be recalled post having been recommended for market authorization. In summary, the research model to be used includes the following three components:

1. SAB characteristics
2. SAB processes
3. SAB effectiveness

4.1. Derivation from literature

The following models existing in literature are of relevance for the proposed research:

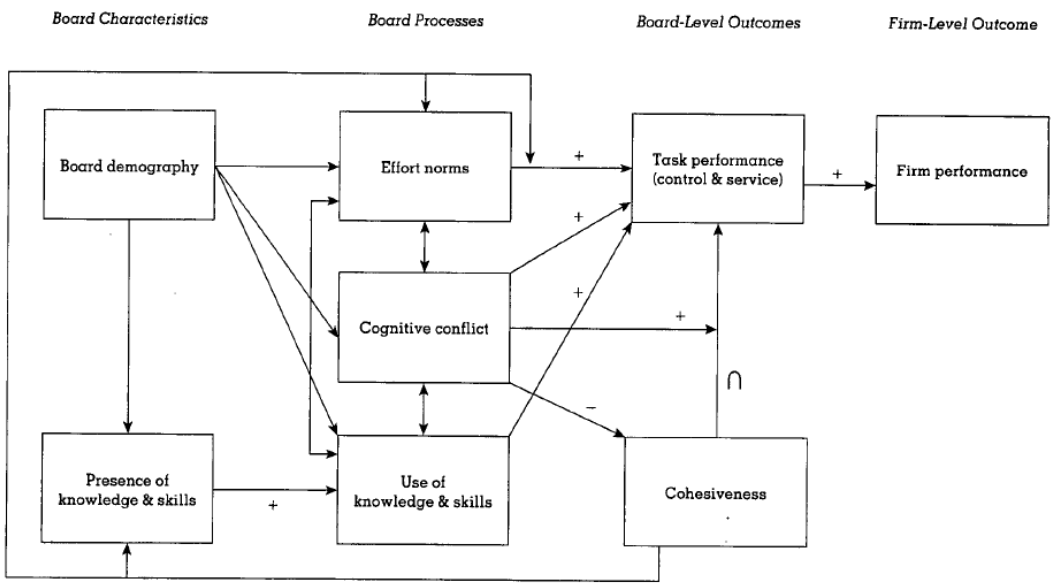

Fig. 4.1 Forbes and Milliken (1999) model of board processes and their impacts on board effectiveness

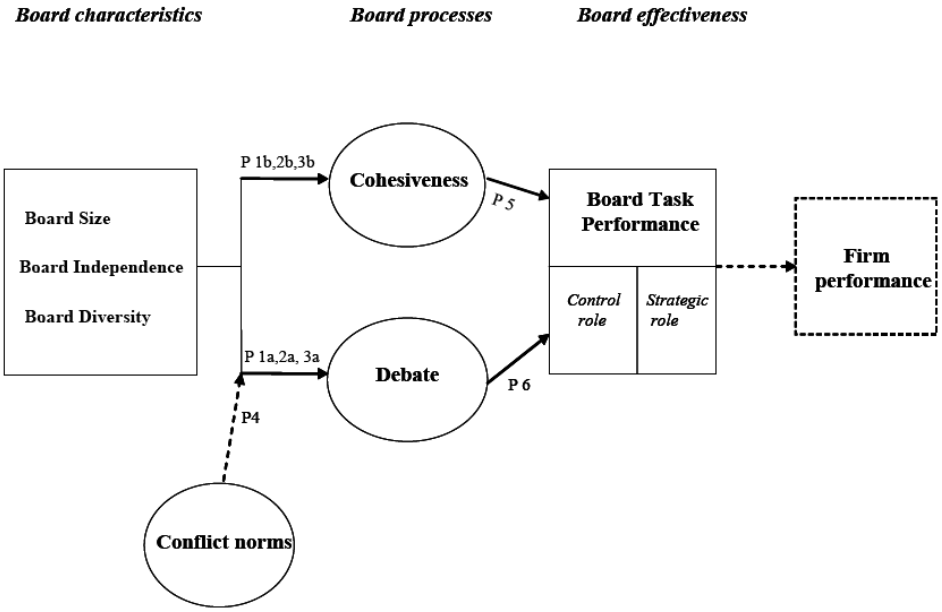

Fig. 4.2 Process-oriented model for board effectiveness, presented by Levrau and van den Berghe (2007)

Both models are based on the input-process-output approach used by scholars studying organizational teams (e.g., Gladstein (1984) and Cohen and Baily (1997), both as cited in Levrau and van den Berghe (2007)).

4.2. Definition and measurement of variables

The table below provides an overview which variables will be relevant for the proposed research, and how these variables will likely be measured:

Variables	*Description and possible measurement options*

SAB characteristics	• Board demography
	  ○ Board size
	  ○ Board diversity

SAB cohesiveness	• Cohesiveness index
SAB effort norms	• Effort as product of motivation of SAB members • Effort norms of support staff • Effort norms of chairperson
SAB debate	• Use of knowledge and skills • Expression of cognitive and constructive conflict • Minority dissent
SAB effectiveness	• SAB task performance in terms of scientific advice ○ Adoption or rejection of AC recommendations by FDA; impact of FDA action (e.g., drug recall)

Table 4.1 Overview of variables relevant for proposed research

The dependent variable: SAB effectiveness

Similarly to a BoD, where **board task performance** "refers to the degree boards are successful in carrying out their strategic and monitoring tasks" (Levrau and Van den Berghe, 2007: 15), SAB board task performance refers to the degree SABs are successful in carrying out their scientific advice tasks to assure the SAB's purpose can be fulfilled. Fulfillment of purpose, or SAB effectiveness, as dependent variable is defined as acceptance (as opposed to rejection) of AC recommendations by the FDA and the consequence of the FDA's decision (no-recall within 5 years or recall within 5 years of approval). The following figure shows possible decisions by an FDA AC and the possible response action of the FDA:

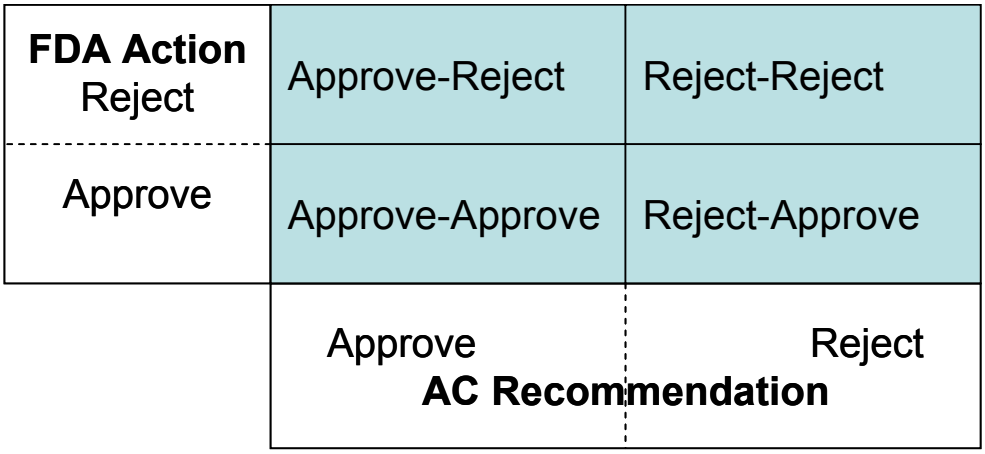

Fig. 4.3 Decision-matrix showing possibilities for AC recommendations and FDA's response

Although it is rare that the FDA decides differently than recommended by the AC, a thorough analysis of the FDA AC database will be conducted to identify situations when an FDA decision was not congruent with AC recommendations (this may be one measure of AC ineffectiveness). A second measure of AC ineffectiveness will be drug recall, within a specified period (e.g., 5 years) after market authorization.

In summary, the following definitions will apply:

- An AC meeting is considered ineffective if AC recommendations are not adopted by the FDA and/or if the approved drug is recalled within a specific period (e.g., 5 years) after market authorization.

- An AC meeting is considered effective if AC recommendations to approve or reject a drug are adopted by the FDA and if the approved drug is not recalled within a specific period (e.g., 5 years) after market authorization.

The independent and control variables describing SAB processes and characteristics

There will be three independent variables describing SAB processes, (1) *cohesiveness*, (2) *effort norms* and (3) *debate*. Control variables such as *board size* and *board diversity* will describe SAB characteristics or demography.

FDA AC transcripts and voting data will be utilized to measure size, diversity (e.g., scientific disciplines), effort norms (e.g., participation or non-participation of members), debate (e.g., number of issues debated, duration of debate, significant minority vote against the majority etc.) and cohesion (e.g., consensus, unanimous vote, etc.). This measurement will be complemented by results obtained from a planned survey research, where SAB members will be asked to evaluate the effectiveness of the SAB they serve on. Levrau and Van den Berghe (2007) suggest that these self-evaluation approaches have been commonly used in previous empirical studies on board effectiveness in the non-profit sector (e.g., Cornforth, 2001; Green and Griesinger, 1996; Bradshaw et al., 1992; Slesinger, 1991; all as cited in Levrau and Van den Berghe (2007)).

Further definitions and descriptions how these variables will be defined and measured are provided below.

Cohesiveness is defined as "the degree to which the members of the group are attracted to each other and are motivated to stay in the group" (Shaw 1976:197; as cited in Levrau and Van den Berghe (2007)). Scholars Forbes and Milliken (1999) define cohesiveness as "affective dimension of members' inclusion on the board (and as) ability of the board to continue working together" (1999:493). The nature of topics to be addressed during SAB meetings require extensive deliberation, and in order to engage in

these discussions, SAB members must bring a minimum level of interpersonal attraction (also see Forbes and Milliken (1999)). Cohesiveness has been found to enhance decision-making to some extent, such as by "promoting earlier and more extensive discussion of alternative scenarios" (Hogg, 1996, as cited in Forbes and Milliken, 1999:496). However, too high levels of cohesiveness might lead to a shift in focus of discussions, from subject topics to rather personal exchanges, which could have a negative impact on effective decision-making. Furthermore, if cohesiveness is too high, cognitive conflict might not be sufficient enough to prevent groupthink, a situation which should be avoided, to make sure the SAB stays focused on the task at hand, and expresses multiple viewpoints and opinions. Thus, a balance is required, which might best be reached at a moderate level of cohesiveness (Janis, 1983, as cited in Forbes and Milliken, 1999).

The measurement of cohesiveness will be based on the four-item cohesiveness index developed by Seashore (1954) and further operationalized by O'Reilly et al. (1989); this cohesiveness index has been used in recent research in the area of Corporate Governance, for example by Levrau and Van den Berghe (2007) or Bettinelli (2011). Survey respondents will be asked to assess cohesion by answering several questions (further details are provided in the sample questionnaire, see appendix). These items will be averaged to form an index of cohesion. Additionally, the analysis of meeting transcripts will provide a means to validate survey findings.

Effort norms are "a group-level construct that refers to the group's shared beliefs regarding the level of effort each individual is expected to put towards a task" (Wageman, 1995, as cited in Forbes and Milliken, 1999:493). According to Kanfer (1992, as cited in Forbes and Milliken, 1999), effort is a product of motivation and refers to the intensity of

individuals' task-performance behavior. Strong effort norms can be expected to contribute to the performance of the board. It is also anticipated that the effort of both the SAB chairperson and support staff are critical contributors to SAB effectiveness. For example, the timely distribution of briefing material (i.e., one of the duties of support staff) and meeting notes (i.e., one of the duties of the SAB chairperson) are important prerequisites for SAB members to do their job in an effective manner.

Effort norms will be measured with the help of meeting transcripts and other information available on the US FDA website, and a survey questionnaire, where respondents will be asked to assess the efforts of SAB members, the SAB chairperson and support staff.

Debate is defined as "an open discussion of task-related differences and the advocacy, by different board members, of differing approaches to the decision-making tasks." (Simons et al, 1999, as cited in Levrau and Van den Berghe, 2007) According to Eisenhardt et al. (1997), debate "facilitates the generation of ideas and provides the opportunity to critically assess multiple alternatives and to question false assumptions" (as cited in Levrau and Van den Berghe, 2007: 18). Research findings suggest that the occurrence of objective debate seems to be positively related with board effectiveness (Finkelstein 2003; Levrau 2007).

The measurement of debate will comprise various aspects, such as *number of issues debated*, *duration of debate*, *significant minority vote against the majority, use of knowledge and skills*, *expression of cognitive and constructive conflict* or *minority dissent*. Consistent with Forbes and Milliken (1999), the *use of knowledge and skills*

refers to "the process by which members' contributions are coordinated" (1999:495), whereas *cognitive conflict* "refers to the content of members' contributions" (1999:496). Thus, the chairperson plays a critical role in assuring that knowledge and skills of SAB members are used effectively throughout each meeting. According to De Dreu and West (2001), *minority dissent* is defined as "instances in which a minority in a group publicly opposed the beliefs, attitudes, ideas, procedures, or policies assumed by the majority of the group. Such a minority could consist of a single individual or several individuals opposing the majority perspective." (De Dreu and West, 2001: 1193) Both meeting transcripts and survey results will be used to measure *debate*.

Board size is defined as the total number of SAB members. According to Levrau and Van den Berghe (2007), the effects of board size can be both positive and negative. While larger boards potentially have a greater variety of skills and an increased amount of expertise at their disposal (Smith et al., 1994, as cited in Levrau and Van den Berghe (2007)), there exists a turning point at which the benefits of a larger board will be outweighed by the costs in terms of productivity losses due to organization and communication challenges (Levrau 2007). Consequently, debate might be impacted negatively, if the board size is too high (also see Hackman, 1990 and Eisenberg et al., 1998; both as cited in Levrau and Van den Berghe (2007)). Scholars Horwitz and Horwitz (2007) confirm that "although large teams can generate more outputs as additional members add resources and skills to teams, additional members also complicate the amount and nature of interaction and coordination, thereby decreasing satisfaction and cohesion among members" (Gully et al., 1995; Magjuka & Baldwin, 1991; as cited in Horwitz and Horwitz, 2007: 997).

Board diversity, according to van Knippenberg et al. (2004), refers to "differences between individuals on any attribute that may lead to the perception that another person is different from self" (e.g., Jackson, 1992; Triandis et al., 1994; Williams & O'Reilly, 1998; as cited in van Knippenberg et al., 2004:1008). Knippenberg et al. (2004) consequently define diversity as "an almost infinite number of dimensions, ranging from age to nationality, from religious background to functional background, from task skills to relational skills, and from political preference to sexual preference" (2004: 1008), but they emphasize that, in practice, diversity research has mainly focused on gender, age, race/ethnicity, tenure, educational background, and functional background (Milliken & Martins,1996; Williams & O'Reilly, 1998; as cited in van Knippenberg et al, 2004). Another definition of diversity is proposed by Harrison and Klein (2007), who use the term diversity "to describe the distribution of differences among the members of a unit with respect to a common attribute, X, such as tenure, ethnicity, conscientiousness, task attitude, or pay. Diversity is a unit-level, compositional construct" (Harrison and Klein, 2007:1199). Mannix and Neale (2005) suggest a broad definition of diversity, which may be applied to any group. They define diversity as "variation based on any attribute people use to tell themselves that another person is different" (Williams & O'Reilly, 1998; Jackson, 1992; as cited in Mannix and Neale, 2005:33). In the context of the proposed research, diversity will be defined as variation on the following attributes of SAB members, which is based on McGrath et al.'s organizing scheme as a framework (McGrath et al, 1995, as cited in Mannix and Neale, 2005:36):

Difference related to	*Attributes*
Social category	• Age • Gender • Ethnic origin
Knowledge or skills	• Education • Scientific knowledge • Information or expertise • Years of experience
Community-status	• Tenure or length of service • Title

Table 4.2 Proposed diversity framework to measure SAB members' diversity

A first overview of planned questions is provided in the draft questionnaire (see appendix).

4.3. Proposed research model

In summary, the following variables will be measured:

Dependent variable	*Independent variables*	*Control variables*
SAB effectiveness	Cohesiveness	Board size
	Effort norms	Board diversity
	Debate	

Table 4.3 Overview of dependent, independent and control variables

The research model to be used is based on both the Forbes and Milliken (1999) model and the Levrau and van den Berghe (2007) model (see above).

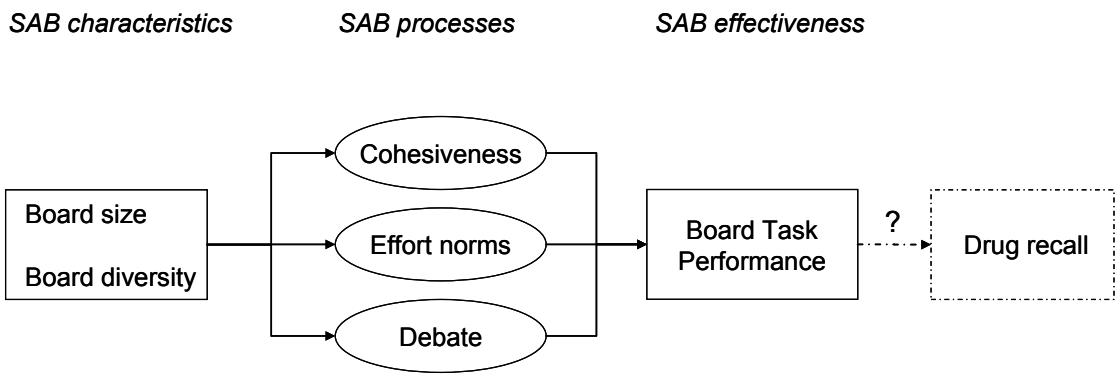

Fig. 4.4 Process-oriented model for SAB effectiveness

5. Research Design

The study design and instrument used in the pilot study showed some weaknesses and it is planned to eliminate these prior to starting the proposed research project. In particular, it was suggested to refine the research instrument by applying further data analysis techniques (Hahn 2011). The author identified linguistic analysis (as used by Broniatowski et al. (2010) in a similar context) and a qualitative approach based on survey research as possible research instrument options. It was planned to study 3-5 FDA ACs in detail, starting with linguistic analysis of meeting transcripts, which would be followed up by survey research. While it is still planned to use these data analysis methods, the selection of particular ACs will now depend on the fact whether these ACs made recommendations for granting market authorization for drugs, which had to be recalled at a later point in time.

5.1. Choice of methodologies and techniques

An empirical survey research methodology supported by both qualitative and quantitative methods will be used, where data will be collected with the help of questionnaires, and subsequently analyzed by using quantitative analysis methods. To validate findings from the survey analysis, meeting transcripts will be analyzed by using elements of content analysis.

This methodology is chosen as no primary data currently exist which could be used as a data source for the proposed research. Furthermore, scholars Levrau and Van den Berghe (2007) suggest that this is a valid approach in a similar context. They recommend to measure board task performance by "identifying various board functions

related to the (board's) role and then asking respondents to assess how well these functions are being performed" (Levrau and Van den Berghe, 2007:16). The fact that these self-evaluation approaches have been commonly used in previous empirical studies on board effectiveness in the non-profit sector (e.g., Cornforth, 2001; Green and Griesinger, 1996; Bradshaw et al., 1992: Slesinger, 1991; as cited in Levrau and Van den Berghe, 2007) provide further support for the choice of this research methodology, especially in terms of its feasibility.

The questionnaire technique seems to be appropriate to collect data for the proposed research, as it allows adapting questions used in previous research (e.g., O'Reilly et al. (1989) or Bettinelli (2011)) to fit the purpose of providing answers for the research question at hand. For example, the variable "cohesiveness" was measured in previous research (Seashore 1954; O'Reilly III 1989) by using the cohesiveness index developed by Seashore (1954). The questionnaire will be comprised of two parts and several sections to gather and assess information related to the target variables outlined in the previous chapter. A draft questionnaire is provided in the appendix.

5.2. Description of data collection

Content analysis

Meeting transcripts and other information available on the US FDA AC website (e.g., charters, briefing material) will be analyzed to collect data related to decisions leading to the approval or rejection of a drug for market authorization. Transcripts will provide information about AC characteristics (e.g., AC size and diversity) and processes (e.g., voting practices as an indicator for cohesion and/or debate), and will also serve as

basis to validate findings from the survey research. Further information is provided in chapter 4 (measurement and definition of variables).

Questionnaire design

The questionnaire will be split into two parts, covering the areas of SAB characteristics and SAB processes. In the first part, data regarding board size and board diversity will be collected. Respondents will either be able to reply directly to a question (e.g., related to age, they should indicate their age to the nearest year), or they will be able to select an answer from available choices (e.g., related to education, ranging from below college education to university degree). In the second part, data expected to contribute to SAB processes will be collected. This will comprise questions related to cohesion, effort norms and debate. The draft questionnaire (see appendix) is an example and will be further refined prior to starting the proposed research.

Sampling and response rate

The author will use her business and research network to gain access to individuals having served as SAB members. The sample will only consist of SABs or ACs dealing with the development of pharmaceutical drug products. SABs in other industries or dealing with other product categories are out of scope for the planned research.

At this point, it is difficult to estimate the exact sample size, partly due to the fact that no comparable survey was done previously with SABs. One way is to look at surveys being done in the area of Corporate Governance. Jonsson (2008), for example, performed a study with BoDs of SMEs in Iceland. His sample size consisted of 560 companies, and

the overall company response rate was 21% (Jonsson, 2008:210), which seems to be in the expected range or even higher, compared to surveys being done by other scholars in the CG field (e.g., Forbes and Milliken, 2003; Geletkanycz, 1998; Hambrick et al., 1993; Koch and McGrath, 1996; as cited in Jonsson, 2008).

For the planned study, a response rate of 20% will be targeted. It is planned to study 3 different types of FDA ACs in depth, investigating three effective and three ineffective meetings (for definitions see chapter 4) for each type of AC. Fink (2009) suggests to conduct a small pilot test using about 25 to 50 individuals, to be able to estimate the standard deviation of the study participants, which can then subsequently be used to calculate the needed sample size.

Administration

As outlined in the pilot study (Hahn 2011), an online questionnaire will likely be used. To avoid isolating the respondents, an effect often occurring with online questionnaires, according to Fink (2009), advance preparation, e.g., in the form of phone calls, is planned. To maximize the response rate, a convenience sampling method will be chosen, i.e., everyone who is available will be selected if survey criteria are met (Fink 2009). Access to questionnaires will be distributed electronically by email. A pilot study is planned to test easy access to and administration of the survey, as well as reception of reliable and valid survey data. It will also help to gain more insight regarding required sample size and feasibility of the approach.

Resource considerations

Major resources required will be time and money – the latter for incentives to be given, and the former for advance preparation and eventual follow-up interviews.

5.3. Survey Design Validity

It will be important to secure both measurement and design validity of the survey. The former will be achieved if the survey instrument is reliable and valid, whereas the latter if the survey context is right. Furthermore, the survey design shall be internally and externally valid. Internal validity is reached when the study's outcome is caused by the variables that are controlled in the study. External validity is reached if study findings apply to other people and other settings (also see Fink (2009)).

Measurement validity

To achieve measurement validity, the content of the survey needs to be comprehensive. Questions need to be stated clearly to avoid misunderstandings or confusion. Also, where possible, the format of possible responses shall be made uniform, using the same measurement scale, to secure consistency throughout the questionnaire. The pilot will help to address potential issues hindering measurement validity.

Design validity

A cross-sectional survey design is planned, i.e., data will be collected at a single point in time. The context in which the planned study will be conducted is pharmaceutical drug development, meaning that only ACs/SABs dealing with drug development aspects

will be selected. Respondents will be selected by using a convenience sampling method, while securing access to the target group with the help of personal contacts.

Internal validity

Internal validity will be reached if the study's outcome, in this case SAB effectiveness, is caused by the variables controlled for in the study, i.e., SAB demography variables (like board size and board diversity) and SAB process variables (like cohesion, effort norms and debate). If the results indicate that the selected research model is not useful, i.e., no internal validity is given, the data analysis will provide insight on how to develop a better model for the proposed research.

External validity

External validity will be reached if the study results can be applied to SABs in other contexts, i.e., industry sectors other than the pharmaceutical industry, or SABs dealing with other topics than drug development.

5.4. Limitations

Possible limitations of the research design relate to data collection and survey validity. Firstly, the sample size might be lower than expected and thus make it difficult to produce meaningful results, or generalize from study findings. Secondly, the administration of the study poses some challenges. As it is planned to use an online questionnaire and not all participants might be reached prior to sending out the questionnaire, there is a risk that these participants might feel isolated or confused when not understanding particular questions. The test pilot will help to mitigate this risk, as

responses from pilot study participants will be used to eliminate confusing questions or improve specific wording prior to starting the main study. Thirdly, threats to both internal and external study validity exist: internal validity might be questioned due to biases resulting from the selection of participants, as the selection process might not be random, or due to the fact of choosing the wrong research model. External validity might be questioned due to the *Hawthorne effect*, which means that respondents may answer atypically because they know that they are participating in the survey.

6. Data Analysis

6.1. Data Interpretation

Data will be available in the form of meeting transcripts and other information derived from the US FDA AC website (e.g., AC charters and briefing material), as well as in the form of responses to online questionnaires. The main goal will be to explain a relationship between the dependent variable *SAB effectiveness* and the independent variables *cohesiveness*, *effort norms* and *debate*, while controlling for *board size* and *board diversity*. To achieve this goal, collected data will be analyzed by using quantitative analysis methods with the help of a statistical software program like SPSS. Statistical tests will include descriptive statistics analysis, regression analysis, variance and correlation. Findings from the statistical analysis will then be validated, for example by applying content analysis methods to meeting transcripts.

6.2. Potential results and their significance

The results will help to understand how SAB characteristics and processes can contribute to *SAB effectiveness*. Understanding better how the composition of an SAB impacts its effectiveness will have a significant impact on the member selection process. It is anticipated that this will be relevant not only in the context of SABs, but also in the broader business context (e.g., when selecting BoD members), where an increased scientific understanding will be needed to solve complex business problems. Ultimately, scientific control tasks might be integrated into Corporate Governance practices, e.g., by establishing a link between SABs and BoDs. Consequently, the results of the proposed research will contribute to better understand elements contributing to board effectiveness

in general – be it SAB effectiveness or BoD effectiveness, and thus to developing a set of recommendations for potential best practices for SAB establishment and management.

6.3. Contingency Plans

Due to existing research in a very similar context (Forbes 1999; Levrau 2007) and the fact that research models exist to study board effectiveness, it can be argued that the proposed research is based on "solid grounds". However, there might still be challenges to be faced that could have a negative impact on the success of the project; major challenges include a low sample size and, consequently, a lack of external validity. The low sample size may lead to a non-efficient response rate in the survey, and consequently impact the generalizability of the data.

Contingency plans include a test pilot, in order to be able to better estimate the needed sample size, and check the comprehensiveness of the questions posed. The author will also use her business and research contacts to gain access to as many SAB members as possible, so as to increase the pool of potential survey participants.

6.4. Areas for further research

According to Pennington (2008), complex problem solving depends on cross-disciplinary collaboration among scientists. She outlines that there is a need for better understanding of team dynamics in multidisciplinary, multiorganizational, and distributed settings. She also emphasizes the complexity of the system and the need to integrate societal and policy interactions, which she refers to as transdisciplinary science. The conceptual model (see Fig. 6.1 below) utilized by Pennington (2008) might be of

relevance for further research, as it describes individual as well as group processes and how these link to collaborative outcomes (i.e., SAB task performance or effectiveness in the proposed research context).

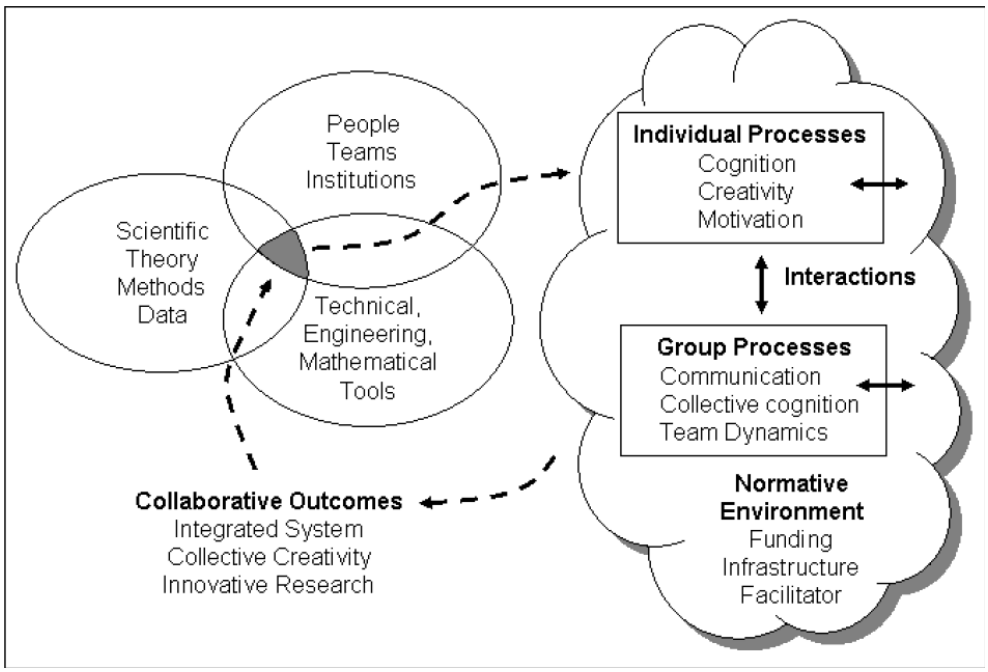

Fig. 6.1 Conceptual model of innovation (Pennington 2008) to describe effective integration of scientific knowledge from different disciplines

Cross-disciplinary collaboration and particularly the area of transdisciplinarity among team members warrant further exploration, as strategic decision-making related to investments in new technologies requires a process to integrate various disciplinary perspectives. In parallel, society requests increased cost-effectiveness and accountability of public and private sector investments based on team initiatives (Stokols et al. (2006)). Thus, the areas of cross-disciplinary collaboration and the "Science of Team Science" are topics that should be considered for further research at a later point.

7. Contribution to Knowledge

According to Remenyi et al. (1998), to obtain a doctorate, a candidate "needs to have undertaken a substantial programme of original research and in so doing produce a dissertation which makes a valuable contribution to the body of knowledge." (Remenyi et al., 1998:248) The authors also outline that the doctoral work needs to be original, either in terms of developing a new theory, relating it to a novel research methodology, or applying the theory and/or methodology in a field which has previously not been studied in this way.

The proposed research will be original in terms of applying theory and methodology derived from the area of Corporate Governance in a new area – that of Scientific Peer Review and SABs. While doing so, the proposed research will contribute to bridging two research areas that are currently unrelated (Corporate Governance and Scientific Peer Review). One might describe this as integrative thinking approach, where a synthesis is built from two opposing ideas, by improving on elements of each (Hilb 2005; Martin 2007; Patterson 2007); in this sense, the proposed research will not only produce a novel approach, but also be able to provide suggestions for improvements in the individual areas of Corporate Governance (i.e., BoD effectiveness) and Scientific Peer Review (i.e., SAB effectiveness).

Ultimately, the proposed research might contribute to the establishment of an "equivalent Sarbanes-Oxley for Science", as proposed by Michaels (2008), who argues that "science is also becoming more like accounting in that it is increasingly and inextricably linked to commerce. Michaels (2008) points out that "(w)e need an

equivalent Sarbanes-Oxley for Science, tough federal legislation that parallels reforms in the accounting trade. Science is the basis for our public health and environmental regulatory system." (Michaels, 2008:244).

8. Time Plan

The following table provides an overview of the research project milestones that are on the critical path:

Critical path milestone	*To be completed by*
Final draft questionnaire is established	Q3/2011
Ethical approval for research is obtained	Q4/2011
Test pilot study is being conducted	Q4/2011
Changes are implemented in questionnaire and final questionnaire is established	Q1/2012
Study participants are selected	Q1/2012
Data collection is completed	Q3/2012
Data analysis starts	Q4/2012
Data analysis is completed	Q1/2013
Write-up of results is completed	Q4/2013

9. Summary & Conclusion

The proposed research aims to evaluate a model for assessing the effectiveness of SAB's. The model is derived from the literature in the area of Corporate Governance, where it was proposed for evaluating BoD effectiveness. It includes measures of SAB characteristics and processes as these may relate to its effectiveness. This model will be evaluated in two different ways: (1) a quantitative analysis will be conducted using the FDA AC database to estimate the extent to which this model can explain observed variability in effective and ineffective AC meetings (a distinction derived from whether FDA's decision to approve a drug was congruent with AC recommendations and if a drug had to be recalled within 5 years after market authorization); and (2) a qualitative survey will be conducted to assess the importance of the model parameters.

It is anticipated that results from this research will provide a first insight into determinants of SAB effectiveness. Given that this topic has not been a subject of significant scholarly attention, this work may also provide an opportunity to highlight the importance of SABs in the broader context of Corporate Governance. This research is anticipated to make scholarly contributions to both theory and management practice: a set of recommendations for potential best practices for SAB establishment and management will be developed. Also, the potential exists that the role of an SAB might be integrated in current Corporate Governance practices as applied to research-intensive companies, thus also influencing Corporate Governance theory.

The importance of this potential contribution can be gauged from the fact that the boundaries between academic science and business are diminishing (also see Michaels

(2008)), investors are increasingly requesting more transparency, not only in terms of financial, but also in terms of scientific accountability. Lack of scientific quality can have a significant negative impact on the financial health of a company. It is therefore important to make sure the collaborative decision-making process in the SAB environment is effective. Complementing a scientific review function to the current functions of a BoD may be considered a relevant topic within Corporate Governance.

10. Appendix

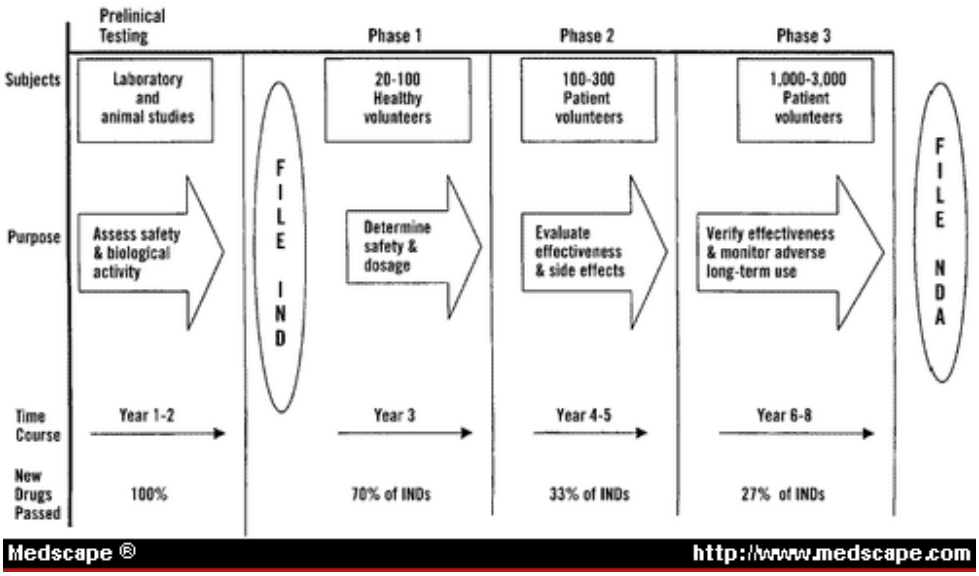

Figure 2.1 Overview of drug development process and review. IND - investigational new drug, NDA - new drug application. Adapted from: The Drug Development Approval Process. Available at http://www.medscape.com/viewarticle/405869_4 (accessed 29 May 2011)

Figure 2.2 Stock price development of company Vertex between March and May 2011

Drug name	*Drug type*	*Maker*	*Market launch*	*When recalled*	*Reason for recall*	*Financial damage*	*FDA AC type*
Baycol	Cholesterol-lowering	Bayer	1997	2001	Severe muscle disorder; responsible for more than 100,000 deaths	Litigation-related damages totaled US $ 1.2 billion	Endocrinologic and Metabolic Drugs AC
Vioxx	Pain reliever for arthritis	Merck	1999	2004	Increased risk of heart attack and stroke	Nearly US $ 6 billion in litigation-related expenses alone	Arthritis Drug AC
Bextra	Anti-inflammatory drug to treat arthritis and pain	Pfizer	2004	2005	Increased risk of heart attack and stroke	Over US $ 2 billion in legal awards and expenses	Arthritis Drug AC
Rezulin	Anti-diabetic and anti-inflammatory drug	Warner-Lambert	1999	2000	Causal connection with hepatitis	N/A	Endocrinologic and Metabolic Drugs AC
Posicor	Drug to treat hypertension	Roche	1997	1998	Deadly effects when combined with any of 25 different drugs	Potential losses of revenues in the amount of US $ 2.9 billion	Cardiovascular and Renal Drugs AC
Propulsid	Relief of nighttime heartburn due to gastroesophageal reflux disease	Johnson & Johnson	1993	1995	Heart-rhythm disorders	N/A	Gastrointestinal Drug Advisory Committee
Avastin	Breast, lung and kidney cancer treatment	Roche	2008	2011	Adverse effects outweighing benefits	N/A	Oncologic Drugs AC

Table 2.1 Examples of significant drug recalls since 1995

Sources:

- http://247wallst.com/2010/12/10/the-ten-worst-drug-recalls-in-the-history-of-the-fda/2/ (accessed 6 July 2011)
- http://www.drugrecalls.com/news-blog/37-news-blog/160-cancer-drug-under-scrutiny.html (accessed 6 July 2011)
- GAO Report on Drug Safety (GAO 2006)

Another Vote Against Roche's Avastin, but Lost Sales Already Incorporated in Our Valuation

by Karen Andersen, CFA | 30 Jun 11

The Food and Drug Administration's oncologic drugs advisory committee unanimously voted Wednesday to recommend the withdrawal of Avastin's approval in breast cancer. Because this panel was largely composed of physicians who voted against retaining this indication at an ODAC meeting last July, we had been anticipating a negative outcome, and we're not making any changes to our fair value estimate for Roche RHHBY .
Roche was granted the hearing as a last venue to argue its case; the firm hoped that the FDA would retain the accelerated approval label while it conducts an additional study. However, panel members did not support this strategy, citing the drug's known side effects and uncertain efficacy as the chief reasons for removing the label. The FDA commissioner, Margaret Hamburg, will make the final decision, which we expect to hear later this summer. Roche still plans to conduct the proposed trial, but data will not be available for at least four years.

Overall, we expect Roche to retain less than half (40%) of its previous 50%-plus share of the U.S. Avastin breast cancer market, with more sales retained via private insurers (which could have more discretion for reimbursement) than from government payers like Medicare and Medicaid. We think Roche could see $400 million in U.S. breast cancer sales for Avastin in 2011, down from roughly $800 million by our estimate in 2010. Our fair value estimate remains insensitive to any further U.S. regulatory pressure in this indication; removing all U.S. Avastin breast cancer sales from our model would not result in a fair value reduction. We think Avastin's sales will be somewhat bolstered by the fact that this indication remains approved in Europe (and was just extended to include combination with a second form of chemotherapy), and prominent groups such as the National Comprehensive Cancer Network in the United States continue to support Avastin's use in breast cancer. We note that the impact is also lessened by Roche's broad portfolio of products; on a global level, Avastin's breast cancer sales constituted roughly 20% of total Avastin sales in 2010, but less than 3% of Roche's overall top line.

In our opinion, both the FDA's center for drug evaluation and research division and Roche had strong arguments at the hearing. We think CDER was unclear with Roche regarding the requirements for converting Avastin's breast cancer label from accelerated to full approval, and that perhaps these requirements have become more challenging since the drug's initial breast cancer approval in 2008. As a result, we think CDER has had difficulty applying approval standards in a uniform way. However, we think CDER is correct to emphasize that Avastin's benefit in most breast cancer studies appears to be minimal, and that the drug's known side effect profile becomes an even more important issue when efficacy is uncertain. In addition, we are disappointed that Roche has delayed exploring more targeted use of the drug in various subsets of patients--for example, those with aggressive forms of breast cancer like triple-negative breast cancer, or those with high levels of certain biomarkers--until after last July's negative ODAC panel meeting.

Figure 2.3 Press article covering an FDA AC vote leading to the recall of breast cancer drug Avastin

Source: http://torontostar.morningstar.ca/globalhome/industry/news.asp?articleid=385759 (accessed 6 July 2011)

Year issued	*Name of Code*	*Content (major, critical aspects)*	*Context*	*Relevance for proposed research*
1992	Cadbury Report	• Operation of main BoD • Establishment, composition and operation of key BoD committees • Importance of non-executive directors • Reporting and control mechanisms of a business	UK	• Code has had great influence on development of other codes
1999	Turnbull	• Internal control requirements • Risk management, esp. related to new risks	UK	• Aspect of risk management
2003	Higgs Review	• Role and effectiveness of non-executive directors • BoD performance and effectiveness • Evaluation of BoD and its individual members	UK	• Aspects related to BoD and individual effectiveness and performance
2003 / 2010	Combined Code (based on Higgs and Smith reviews)	• Formal and rigorous annual evaluation of BoD, its committees, and individual members • Latest version of the code was issued in May 2010 and is available on the Internet[3]	UK	• Annual evaluation practices, risk management approach
1999 / 2004	OECD Principles of Corporate Governance	• Effective CG framework • Rights of shareholders • Role of stakeholders in CG • Disclosure and transparency • Responsibilities of the BoD	Global, publicly traded companies	• Effective framework • Disclosure and transparency • Responsibilities of the board
2002	Winter Report	• Nomination of directors • Remuneration of directors • Share option schemes • Transparency • Voting	EU, listed companies	• Transparency • Voting practices
2002	Sarbanes-Oxley (SOX)	• Auditor independence • Financial compliance	US and non-US	• Independence aspect

[3] Source: http://www.frc.org.uk/corporate/ukcgcode.cfm (accessed 16 June 2011)

		• Rotation of audit partners	companies with US listing	
2003	NYSE CG Rules	• Independence of directors • Required committees (e.g., nominating/CG, compensation, audit) • Committee purpose to be documented in charter • Annual evaluation practice	US	• Documentation of committee purpose • Annual evaluation practices
2008	NACD Key Agreed Principles to strengthen CG	• BoD responsibility for CG • Transparency • Director competency and commitment • BoD accountability and objectivity • Independent BoD leadership • Integrity, ethics and responsibility • Attention to information, agenda and strategy	US, publicly traded companies	• Transparency • Competency and commitment • Objectivity • Responsibility • Attention to strategy

Table 3.1 Overview of Corporate Governance codes relevant for proposed research, based on (Mallin 2010)

Sample questionnaire – this is an illustrative example only which will be further updated prior to starting the proposed research!

PART A: SAB characteristics

- Please indicate your age to the nearest year _____
- Gender Male / Female
- What is your ethnic origin? White / Asian / Black / Chinese / Mixed / Other (Specify)
- What is the highest educational qualification you have? None / High School / College / University Degree / Other (Specify)
- Describe your scientific knowledge _____
- Describe other skills you have _____
- How many years of experience do you have in your area? 0-5 / 6-10 / 11-20 / above 20 years
- What is the length of service in your current profession? 0-5 / 6-10 / 11-20 / above 20 years
- Please indicate the title(s) you have _____
- How many SAB members are on the SAB you serve on*)? _____

*) If you serve on more than one SAB, please select the one where you spend most of your time on

Sample questionnaire – this is an illustrative example only which will be further updated prior to starting the proposed research!

PART B: SAB processes

INSTRUCTION: You will find a number of items in this questionnaire asking about your views related to the SAB you serve on. Please respond to each statement by choosing the appropriate rating scale. Please only mark one box for each statement.

	Strongly agree	**Agree**	**Slightly agree**	**Neither agree nor disagree**	**Slightly disagree**	**Disagree**	**Strongly disagree**	**N/A**
Cohesiveness								
SAB members are ready to defend each other from criticism by outsiders	7	6	5	4	3	2	1	X
SAB members help each other on the job	7	6	5	4	3	2	1	X
SAB members get along with each other	7	6	5	4	3	2	1	X
(…)	7	6	5	4	3	2	1	X
Debate								
SAB members use their knowledge and skills during meetings	7	6	5	4	3	2	1	X
SAB members express their opinions freely	7	6	5	4	3	2	1	X
SAB members speak up if they don't agree to something	7	6	5	4	3	2	1	X
Discussions during the SAB meetings are constructive	7	6	5	4	3	2	1	X
Different SAB members express different approaches to the topics discussed	7	6	5	4	3	2	1	X
Individual SAB members disagree with the rest of the SAB	7	6	5	4	3	2	1	X
(…)	7	6	5	4	3	2	1	X

Sample questionnaire – this is an illustrative example only which will be further updated prior to starting the proposed research!

PART B: SAB processes (continued)

Effort norms								
I usually read the Briefing Material prior to attending the SAB meeting	7	6	5	4	3	2	1	X
Every SAB member is well prepared and has read the Briefing Material prior to attending the SAB meeting	7	6	5	4	3	2	1	X
The Briefing Material is distributed ahead of time to allow enough time for adequate preparation for the SAB meeting	7	6	5	4	3	2	1	X
The questions to be answered during an SAB meeting are stated clearly in the Briefing Material	7	6	5	4	3	2	1	X
The questions to be answered during an SAB meeting are stated clearly during the SAB meeting	7	6	5	4	3	2	1	X
The SAB chair makes sure all SAB members contribute to the discussion	7	6	5	4	3	2	1	X
The SAB chair is a good facilitator of the meeting	7	6	5	4	3	2	1	X
The SAB chair makes sure SAB recommendations are summarized at the end of the meeting	7	6	5	4	3	2	1	X
Support staff provides necessary information on time so that effective recommendations can be given	7	6	5	4	3	2	1	X
Meeting notes are distributed in a timely manner to allow timely follow-up and preparation for the next meeting	7	6	5	4	3	2	1	X
(…)	7	6	5	4	3	2	1	X

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