

What Vendor Surveillance can learn from:

Basel Accord of Banking Supervision principles for risk management

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ABSTRACT

With the increasing corporations between sponsor and vendor in the pharmaceutical industry, the necessary of a well-developed framework to regulate such corporations drew our attention. The Regulator in finance industry, the Basel Committee on Banking Supervision (BCBS), published its first international capital adequate standard Basel I in 1988 (Kaplan 2018). During these 30 years the standards have already evolved to Basel III, which established a more comprehensive foundation of risk managements than Basel I. Therefore, the Vendor Surveillance in pharma can learn a lot from BCBS.

INTRODUCTION

Published in Apr 2019, the consolidated Basel framework provides a comprehensive guidance for banking supervision. It is the latest global standards for current bank systems. It includes also modeling and reserved capital calculations in market risk, credit risk and operational risk, which may or may not be applicable to pharmaceutical industry.

However, the Basel committee published a manual called *Core principles for effective banking supervision* (the Basel Core Principles) in 2012, which established the framework for regulation and risk management in banks. The core principles provide a minimum standard for sound supervisory in practice. The first 13 principles are imposed for supervisory responsibility and authority clarification. It could be applied to Vendor Surveillance in pharmaceutical industry, if the sponsor act in the role of supervisor as in the principles.

IMPLEMENTATION OF BASEL PRINCIPLES

Principle 1- Responsibilities, objectives and powers. An effective system of supervision with objectives and responsibilities crystal clear is necessary. The supervisor should keep a legal framework in place to conduct ongoing supervision. ((BDBS), 2012)

- While this principle is applied to vendor surveillance, a well-defined surveillance alliance manual, surveillance plan and risk management culture should be maintained.
- The manual must consist sections of legal topics to ensure the sponsor authority. Each party should have clearly defined responsibility and objectives in the manual.
- To ensure the soundness and success of a study delivery, the sponsor should have the full access to vendor's study team staff list, management, records of overall activities, internal QC and vendor's surveillance plan. In addition, the sponsor can have its own judgement if the vendor is taking unsafe or unagreed actions that affect the delivery.

Principle 2- Independence, accountability, resource and legal protection for supervisors. The legal framework should contain protection for the supervisor to perform independent, transparent processes, sound governance. ((BDBS), 2012)

- Equivalently, we must ensure the legal section in vendor surveillance authorizes the sponsor to conduct surveillance with no concern of permission. In other words, there should be no boundary to interrupt the soundness of supervision.

- The change of members and head(s) of sponsor must be transparent. Unless physically or mentally disabled, guilty of misconduct, or breaching the law, his/her term of supervisory should not be removed. This piece of information should be announced publicly.
- The sponsor also should keep adequate budgets to maintain an effective oversight. Considering of the vendor's risk profile could help the sponsor to determine resource allocations.

Principle 3- Cooperation and collaboration. Domestic authorities and foreign supervisors follow the framework of collaboration to protect confidential information. ((BDBS), 2012)

- There should be evidence existing to prove an agreement of cooperation is in place.
- The sponsor must take reasonable step to ensure released confidential information is treated confidential.
- In terms of receiving confidential information, the sponsor should not disclose any to third parties without agreed permission.

In summary of the first three principles, sponsor should keep risk management culture throughout the study, establish surveillance alliance manual with legal section, and an effective surveillance plan.

Principle 4- Permissible activities. The permissible activities of institutions must be clearly defined. And the use of certain words in names is regulated. ((BDBS), 2012)

- This principle can be applied with respect to the qualification of vendor. Not all contract research organizations can take the role of vendor in a cooperation with the sponsor company. The type and size of its business should be fully examined before it was selected. However, the details will not be considered in this publication.

Principle 5- Licensing criteria. The authority can setup criteria for licensing. The process should at least include an assessment of ownership fitness. To be specific, it should include evaluation of vendor's risk management, strategy plan and financial conditions. ((BDBS), 2012)

- The original principle ensures the licensing authority the power to supervise qualification of banks and to revoke the banking license under certain circumstances. This is a necessary step to avoid license a shell bank.
- Equivalently, during the surveillance process, the sponsor should have the authority and appropriate process to perform an assessment of vendor risk management profile, and to review their strategic and operating plans.
- In addition, the management and study research staff should be evaluated by the sponsor as well. The criteria include but not limited to: (i) skills and experience of members; (ii) records of past successful deliveries. More details will be interpreted in the next part.

Principle 6- Transfer of significant ownership. Within the framework, the supervisor's power should be defined such that the sponsor can review and reject on any proposal of ownership transfer in the counterparty. ((BDBS), 2012)

- Any changes that may negatively affect the stakeholders in surveillance should be notified to sponsor immediately as soon as the vendor became aware of the situation. So that the sponsor can take appropriate action to evaluate risks and make necessary changes to surveillance.
- Periodic reports or on-site examinations are expected to be provided, so the sponsor can keep track of ongoing studies.

In summary of principle 4, 5 and 6, qualification and trustfulness of the vendor should be fully examined by reports and on-site visits from the sponsor. Vendor is also expected to provide a proposal including its internal control and its strategic plan for stress situation such as key study staff leave or resign during surveillance. And the sponsor can give penalty to the vendor if that circumstance occurs. In extreme conditions it did happen, the vendor is supposed to prove the qualification of replaced staff. In other words, both a proper transition plan and a qualified resume should be in place.

Principle 7- Major acquisitions. Originally the supervisor should be authorized to approve or reject major acquisitions or investments by a bank. ((BDBS), 2012)

- When applying it to the vendor surveillance., it can be interpreted as the acquisitions of vendor. One possible extreme situation is that the acquisitions of vendor with another CRO during the surveillance process. In a recent report, a large global CRO made over 20 acquisitions over the last twenty years. (China, March 2019). Large CRO tends to have more resource for programming but might also prefer expending its business by merging and acquiring. Hence, vendor surveillance should consist a section clearly defining the strategic plan for acquisitions and investments.
- Additional risk evaluation to the vendor is expected to be conducted before and after the acquisitions and investments. Therefore, the sponsor can determine if they will hinder the effective supervision.

Principle 8- Supervisory approach. The supervisor should develop and maintain a forward-looking assessment of the bank risk profile. ((BDBS), 2012)

- The sponsor should be able to predict repetition of mistakes from vendor by learning from past experience, or from past study issue logs. In this way the sponsor can keep a plan in place for early intervention. If it is the same vendor and for similar studies, in the best case, the sponsor can make a list of potential common programming issues ahead to monitor risks.
- A comprehensive framework can assist the sponsor to build a process to handle stress situations timely.

Principle 9- Supervisory techniques and tools. Appropriate techniques should be implemented for surveillance purpose. ((BDBS), 2012)

- It doesn't matter how the supervision styles are, on-site, off-site, or mixed. The sponsor takes the responsibility to develop and utilize the updated software.
- And the sponsor is also responsible for developing an automated tool for checking data against its own standard, or global standard whichever stricter. The tool is expected to detect and report

metadata issues, control terminology issues in data spec for programming efficiency. For better case there can be tools to detect TLF inconsistency intelligently instead of human manually check.

- During surveillance, automated tools are on the top list in recent years because of A.I. trending. The tool can be either developed in SAS or R.
- The sponsor communicates findings with the vendor to determine follow-up works in a timely manner.
- A periodic audit, internally or externally, is also considerable for the sponsor.

Principle 10- Supervisory reporting. The supervisor should collect and analyze reports from vendor and keep it documented. ((BDBS), 2012)

- The surveillance plan or alliance manual should ensure the sponsor enough power to request updates from the vendor at regular time phase and on demand. Deliveries such as Dry Run can be updated according to sponsor's comments, both at pre-determined time points, and any time before disclosure.
- The sponsor is responsible for providing standards and instructions for reports, and for reviewing and verifying the report quality. In practice the sponsor is supposed to deliver comments in a timely manner and keep the feedback in place for further references.
- Again, automated tools can play a very important role in this step for evaluation vendor's work in an efficient and accurate way.
- The sponsor requires the vendor to maintain a sound internal supervision of delivery quality. That is to say, the vendor should control and document its own surveillance of delivery production. And the sponsor can assess such reports on a request basis.
- A separate process should be reviewed periodically to evaluate sponsor's satisfactory of surveillance.
- In terms of bringing in external experts to contribute in surveillance, their responsibility, scope of work should be defined clearly and documented.

Principle 11- Corrective and sanctioning powers of supervisors. In banks the supervisor should identify potential risks at an early stage, with supervisory tools for timely correctives. And the supervisor has the power to recommend revocation of the banking license. ((BDBS), 2012)

- By applying it to vendor surveillance, the sponsor is expected to raise up issues early and has the authority to terminate the corporation between the sponsor and vendor.
- If the vendor is not acting in compliance to the alliance manual, or falling below the threshold of satisfactory, the sponsor should have a range of actions to choose under such scenarios. The actions should include but not limit to, restricting the payments, or adding stringent limits in delivery, restricting the power of vendor managements, etc.
- The sponsor should address corrective actions taken by the vendor in a written document.

Principle 12- Consolidated supervision. The word consolidate is the key. Banking supervisory should include supervising the bank on a consolidated basis, adequately monitoring, and applying appropriate standards to business. ((BDBS), 2012)

- The sponsor should understand the overall structure of the vendor group to control risks.
- In case of cross countries corporations between the sponsor and vendor, visiting the vendor's office to perform oversight is an option.
- The sponsor has the option to limit activities of vendors if vendor's exposure to risks are over the threshold, or not promptly managed.

Principle 13- Home-host relationships. The effective supervision information should be shared across local and international entities.

- For global sponsor companies, the same surveillance process should be consistent no matter of geographic locations.

CONCLUSION

By learning from the first 13 principles of banking supervision under Basel Committee, vendor surveillance at pharmaceutical industry should consist several key parts to guarantee a qualified delivery. First, legal section can not be missing from the manual that bounds the vendor and sponsor. A risk management culture should exist throughout the whole course of surveillance. Second, vendor stress plan also should not be missing from the manual. The vendor must reinforce its risk management profile by providing strategies in extreme situations. And the sponsor has the choice to reject the corporation if such a plan is not in contract.

At mean time the sponsor should develop appropriate tools for surveillance evaluation, which includes data quality and output consistency checking. SAS has many products for different needs of analysis purpose.

In the end, the surveillance process should be consistent across one company globally.

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