Microlearning deck
EFPIA Code of Practice
CHAPTER 3

Non-Interventional Studies (NIS)

Non-Interventional Studies: What, Who, How

WHAT is a NIS?

NIS is a study where the Medicinal Product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation.

The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the Medicinal Product is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures must be applied to the patients, and epidemiological methods must be used for the analysis of collected data.

WHY (rationale)

Research activities must remain non-promotional; their aim is to analyse data and improve patient care, not promote a product.

Scientific Independence, transparency, and patient care focus are key to ensure NIS are conducted appropriately.

All stakeholders involved should uphold the principles and rules from the EFPIA Code: Pharmaceutical company, HCPs, HCOs, POs, and anyone planning, or reviewing NIS.

HOW to comply - key rules to follow

Transparency: The involvement of Member Companies with NIS should be transparent and comply with applicable rules on ToVs, funding and disclosures.

Independence: NIS must be based on science and conducted independently of any product promotion or sales activities (Non-promotional).

ToVs to HCPs or HCOs involved in NIS must be justified, transparent, and disclosed as required by National Codes. For disclosure purposes, EFPIA code distinguishes between prospective NIS and retrospective NIS

Prospective NIS collecting patient data from or through HCPs for the study must meet specific criteria. A **Study Plan** should be prepared upfront and, if applicable, submitted to the ethics committee. Company's Scientific services should also approve the plan and supervise the conduct of the study.

- **Study results** should comply with the requirements covering the analysis, how the summary must be shared with HCPs who participated and the availability to self-regulatory bodies or supervising committees.
- If the **results can impact benefit–risk assessment**, the summary must be forwarded immediately to the relevant competent authority.

For all other types of NIS, such criteria is encouraged to the extent possible.

Non-Interventional Studies

Real Life Scenarios

Q1: Can a company fund an NIS spearheaded by a hospital and publish results to inform practice?

A: Yes.

Provided the study is non-promotional, data-driven, and ToVs are disclosed appropriately.

Q2: May a company reimburse travel for a physician participating in NIS meetings?

A: Only if it is a reasonable, necessary travel, directly related to the NIS and within applicable host-country meal/travel policies, and transparently disclosed.

Q3: Should the report of a prospective NIS be shared with authorities too, or only involved HCPs?

A: If the study shows results that are important for the assessment of benefit-risk, the summary report must be immediately forwarded to the relevant competent authority.

Q4: What role can a sales representative play in NIS?

A: Sales representative may facilitate the administration of an NIS, but should not influence its scientific design, investigator selection, conduct or outcomes, and its involvement must remain clearly separated from promotional activities.

Q5: What criteria should companies take into consideration when selecting an investigator for an NIS?

A: Investigator selection must be based on objective, scientific criteria alone. The selection should be documented. The use of predefined criteria and the decision rationale should be transparent.

Q6: Are ToVs related to Prospective and Retrospective NIS disclosed in the same way?

A: For Prospective NIS, ToVs are considered R&D-related and are consequently disclosed in aggregate.

For Retrospective NIS, ToVs are disclosed by name under the applicable categories. More details are available on page 41 of the EFPIA Code.

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Curious to know more about Non-Interventional Studies?

Please refer to following link or connect with your Ethics & Compliance Officer:

Chapter 3 (article 18), pages 24
Annex B Guidance on disclosure of NIS

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