NIS Considerations - Russia
An overview of the considerations when conducting Non-interventional Studies in Russia

Stuart McCully • Compliance Healthcheck Consulting UK Ltd • NIS-C-RU-2012
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LAW ON THE CIRCULATION OF MEDICINES
GUIDANCE ON THE CONDUCT OF NIS IN RUSSIA
Russian Association of Clinical Trials Organisations (ACTO)
Russian Society for Pharmacoeconomics Research (RSPOR)
Conduct of Non-interventional Post-authorisation studies

Mannheimer Swartling (Legal Firm)

Are NPA Studies still allowed after the Law enters into force, or do they need to comply with the requirements of the Law?

Where is the borderline between the non-regulated NPA Studies and the regulated phase IV clinical trials and who determines this?

What are the requirements to properly conduct NPA Studies in Russia?

Differentiation Between the Post-authorization Studies

Challenges to Consider when Planning NIS in Russia

Recommended Standards for the Conduct of NIS in Russia

Recommendations of the EFPIA Code of Practice

FSA Code

Lif Code of Practice

AIPM Code of Practice

IFPMA Code of Practice

NIS: Recommended Standards to Adopt in the Absence of Russian Legislation

HOSPITALITY AND RELATED PAYMENTS

What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

Is it possible to pay for a doctor in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

Is it possible to pay doctors to take part in post marketing surveillance studies? What rules govern such studies?

Is it possible to pay doctors to take part in market research involving promotional materials?
Is there a requirement in law and/or self-regulatory code for companies to make publicly available information about donations, grants, benefits in kind or any other support provided by them to health professionals, patient groups or other institutions? If so, what information should be disclosed, from what date and how?

BEST PRACTICE CONSIDERATIONS - USEFUL LINKS

NIS Definitions

EUROPEAN NIS DEFINITIONS

NIS DEFINITIONS

Non-interventional Study (NIS)

Post-authorisation Safety Study (PASS)

Post-authorisation Efficacy Studies (PAES)

Common NIS Terminology

COMMONLY USED NIS TERMS

COMMON NIS TERMINOLOGY
Disclaimer

Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinions as to the current operative laws, regulations, or guidelines of any jurisdiction. In addition, because new standards are issued on a continuing basis, this Compilation is not an exhaustive source of all current applicable laws, regulations, and guidelines relating to non-interventional studies. While reasonable efforts have been made to assure the accuracy and completeness of the information provided, researchers and other individuals should check with local authorities and/or research ethics committees before starting research activities.
## Regulatory Requirements

### Country-Specific Regulatory Requirements

## Regulatory Bodies

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<th>Competent Authority</th>
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<td>Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor)</td>
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<td>Research Ethics Committees</td>
<td>Federal Ethics Committee (Also referred to as the Central Ethics Committee (CEC) or National Ethics Committee (NEC))</td>
</tr>
<tr>
<td>Data Protection Agency</td>
<td>The Federal Service for Supervision in the Sphere of Telecom, Information Technologies and Mass Communications (Roskomnadzor)</td>
</tr>
<tr>
<td>Pharmaceutical Self-Regulation Body</td>
<td>The Association of International Pharmaceutical Manufacturers (AIPM)</td>
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DEFINITION

Clinical Trials of Medicinal Products

Clinical trials of a medicinal product are studies of diagnostic, therapeutic, prophylactic and pharmacological properties of a medicinal product in the process of use thereof by a human being or an animal, including, but not limited to the processes of absorption, allocation, modification and excretion, by means of scientific methods of assessment for the purpose of obtaining evidence of safety, proper quality and efficacy of the medicinal product, data on anticipated side effects resulting from the use of the medicinal product by a human being or an animal, and the effect of interaction thereof with other medicinal products and (or) food substances, or animal food substances (as per Article 4.41 of the Law on Circulation of Medicines, 2010).

Post-registration Clinical Trial of a Medicinal Product

Post-registration clinical trial of a medicinal product for medical use is a clinical trial of a medicinal product for medical use conducted by the manufacturer of the medicinal product which is put in civil circulation after the state registration, for the purpose of additional collection of data on its safety and efficacy, extension of indications of such medicinal product, as well as for the purpose of revealing adverse reactions of the medicinal product on the patients (as per Article 4.44 of the Law on Circulation of Medicines, 2010).
LAW ON THE CIRCULATION OF MEDICINES

On the 1st September 2010 the Law on the Circulation of Medicines (No. 61-FZ of 12 April 2010) came into force. This law defines “post-registration clinical trials” and requires that these types of studies be approved and conducted in the same way as clinical trials. What the Law has failed to do is differentiate between interventional post-registration studies and non-interventional studies.

Applicability of the Law on the Circulation of Medicines

As a result, there is now confusion as to the applicability of the Law to non-interventional studies. It is generally accepted that the Law does not apply to observational non-interventional studies unless the manufacturer/ sponsor wishes to use the results of such studies in support of submissions to the Ministry of Health and Social Development. In such cases, the Law should be complied with.

Laws Regulating Non-interventional Studies

According to the Executive Director of the Russian Association of Clinical Trials Organizations (ACTO):

“Non-interventional studies are not regulated by the Law “On the Circulation of Medicines”. So, you can’t get an approval for such studies from our Ministry of Health. The Council on Ethics (central) also does not approve such trials. However, it is desirable to obtain ethical approval from the local ethics committee. Patients insurance for such type of studies is not required too.”

[Personal communication of 14 August 2012]
Data Privacy Considerations

DATA PRIVACY AND DATA PROTECTION CONSIDERATIONS WHEN CONDUCTING NIS IN RUSSIA

DEFINITIONS

Personal Data

Personal data is any information pertaining to identified or identifiable with the help of said information natural person (personal data subject), including his surname, given name, patronymic, date, month, year and place of birth, home address, family & social & property status, education, profession, income, other information (as per Leonidchenko, 2010 and Article 3 of Federal law of 27.07.2006 No. 152-FZ).

Sensitive Personal Data

Sensitive personal data means personal data relating to:

- race or ethnic background
- political opinions
- religious beliefs
- health condition
- sexual life
Processing

Processing is anything that may be done to or with personal data, inter alia gathering, putting into order, collecting, storing, updating, using, distributing (including transfer), depersonalizing, blocking or erasing such data (Leonidchenko, 2010).

Operator

Operator is the entity which manages and/or performs data processing, as well as determines the purposes and manner of data processing. In most cases both supervising company and the entity which operates the relevant direction or service are regarded as operators (Leonidchenko, 2010).

Personal Data System

Personal data system is data system which includes personal data recorded in the database as well as information technologies and technical means which are used for processing of said data (Leonidchenko, 2010).

RUSSIAN DATA PROTECTION AGENCY

Data Protection Agency (Roskomnadzor)

The Federal Service for Supervision in the Sphere of Telecom, Information Technologies and Mass Communications (Roskomnadzor) has been established in accordance with Russian President’s Decree No. 1715 of 03 December 2008.

Roskomnadzor is a federal executive authority entitled to carry out permitting and licensing activities, validation and supervision in the spheres of telecommunications, information technologies and mass communications.

Roskomnadzor is an authorized agency entitled to protect personal data owners’ rights.

Under the jurisdiction of the Ministry of Telecom and Mass Communications of the Russian Federation, Roskomnadzor’s activities are aimed at attaining the following objectives:
IMPORT AND EXPORT OF BIOLOGICAL MATERIALS

General Considerations

Biological materials shall be imported (exported) to be researched inside or outside of the Russian Federation, based on permits issued by the Ministry of Healthcare and Social Development of the Russian Federation:

- Permits to import/export biological materials shall be issued for the time of clinical trials of a medicinal product for medical use expected to produce biological materials
- Permits to import (export) biological materials shall be issued for presentation to the customs agencies of the Russian Federation.

(as per Rule 2 of Decree No. 673 of September 3, 2010).

Challenges for Non-interventional Studies

Non-interventional studies are not regulated by the Law “On the Circulation of Medicines”. So, you can’t get an approval for such studies from our Ministry of Health. The Council on Ethics (central) also does not approve such trials. However, it is desirable to obtain ethical approval from the local ethics committee.
Best Practice Considerations

BEST PRACTICE CONSIDERATIONS WHEN CONDUCTING NIS IN RUSSIA

LAW ON THE CIRCULATION OF MEDICINES

On the 1st September 2010 the Law on the Circulation of Medicines (No. 61-FZ of 12 April 2010) came into force. This law defines “post-registration clinical trials” and requires that these types of studies be approved and conducted in the same way as clinical trials. What the Law has failed to do is differentiate between interventional post-registration studies and non-interventional studies.

As a result, there is now confusion as to the applicability of the Law to non-interventional studies. It is generally accepted that the Law does not apply to observational non-interventional studies unless the manufacturer/sponsor wishes to use the results of such studies in support of submissions to the Ministry of Health and Social Development. In such cases, the Law should be complied with.

GUIDANCE ON THE CONDUCT OF NIS IN RUSSIA

Russian Association of Clinical Trials Organisations (ACTO)

According to guidance provided by the Executive Director of the Russian Association of Clinical Trials Organisations (ACTO) on 14 August 2012:

“Non-interventional studies are not regulated by the Law “On the Circulation of Medicines”. So, you can’t get an approval for such studies from our Ministry of Health.

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