

Federal State-Funded Institution
«Scientific Centre for Expert Evaluation
of Medicinal Products» under the Ministry
of Health of the Russian Federation



## **Expert Evaluation of Medicinal Products**

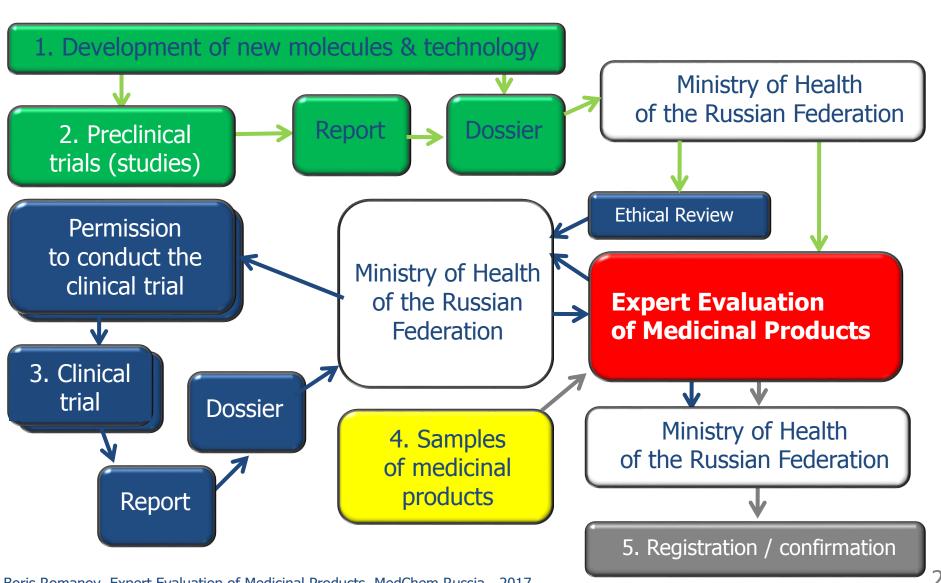
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## **Life Cycle of Medicinal Products**

Development steps: 2016-2021





## **Expert Evaluation of Medicinal Products**

- Expert evaluation of preclinical studies results and documents for conducting clinical trials in Russia (including IMCTs).
- Examination of drug authorisation documentation and post-authorisation changes (quality, efficacy & safety).
- Documentary and laboratory expert evaluation of drug quality during authorisation
- Evaluation of interchangeability ("Russian "Orange Book")
- Maintenance of the Drug Register in Russia
- Certification of immunobiological drugs
- ☐ Scientific activities: research, development of monographs and other texts for the Russian Pharmacopoeia, publication of three scientific journals
- Educational work





## **Methods of Expert Evaluation**





