

Conducting successful trials in Russia

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Wyeth
Research

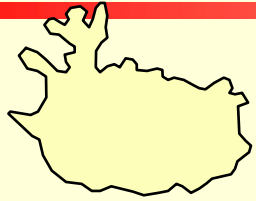
Agenda

- **Wyeth AB**
- **How to get to Russia**
- **Where to go in Russia**
- **Agency and Ethical Committees**
- **Financial Agreements**
- **Laboratory Issues**
- **Safety Reporting**
- **Communication with CRO**
- **Quality of the data**
- **Personal reflections**

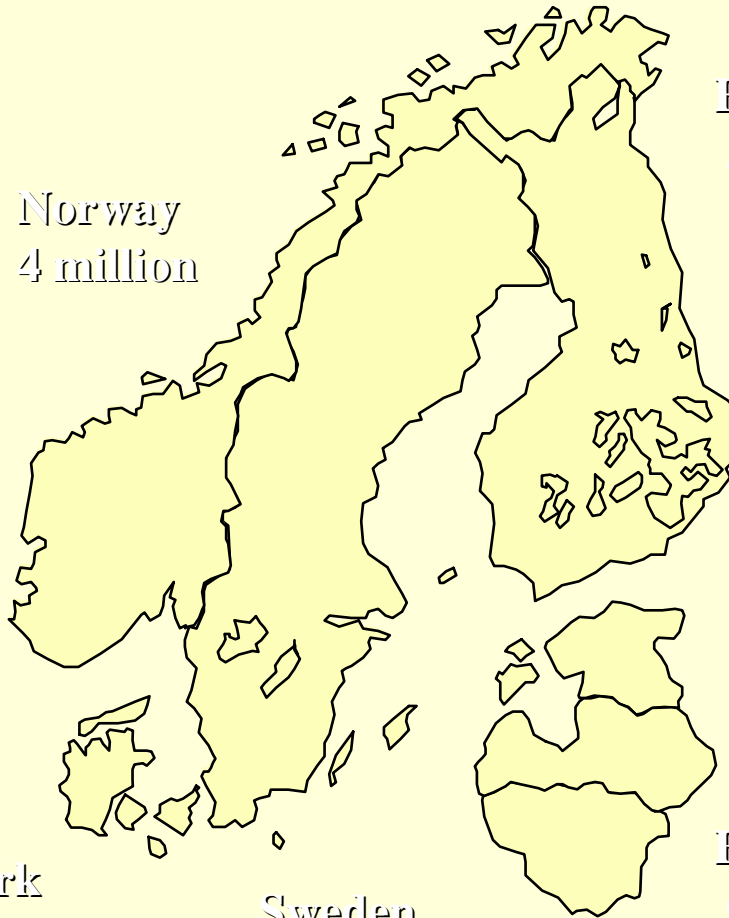
Russia

- **Wyeth AB Sweden**
- **CR&D**

WYETH CR&D NORDIC REGION



Iceland
0.27 million



Norway
4 million

Finland
5 million

Denmark
5 million

Sweden
9 million

Baltic States
6 million

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Russia

HOW TO GET TO RUSSIA

- 1-year Visa

Where to go in Russia



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Russia Agency

- **Ministry of Health of the Russian Federation**

- ▶ Permission of Study Approval
- ▶ Import License
- ▶ Export License

- **FGU Scientific Center**

Federal State Institution Scientific Center of Examination of Medical application drugs

- ▶ Protocol and Amendments

Russia Ethical Committee

- **Central Ethical Committee**

- ▶ Approval centrally before submission to local ethical committee.

- **Local Ethical Committee**

- ▶ Some sites have Local EC

- **Local Ethical Committee delegation to CEC**

- ▶ Local EC can delegate the responsibility to the Central EC at their first approval of the study.

Financial Agreements

- **With Principle Investigator**
- **With the Hospital**

LABORATORY ISSUES

- **Export License**
 - ▶ For Moscow and/or S:t Petersburg
- **Proforma Invoices**
- **Spelling**

Russia Safety Reporting Requirements

- **No Russian law for safety/CIOMS reporting**
- **Praxis: Through personal correspondence it is often advised to follow the relevant European requirements in regarding criteria (SUSAR) and timelines (7/15 days).**
- **No unblinded reports are required. (Blinded are preferred).**
- **No possibility now or in the near future to submit CIOMS reports by fax, email or couriers except personal delivery.**
- **It is unclear how those reports are reviewed and filed at the BoH and central EC.**

- **Communication with CROs**

Russia

- **Quality of the data**

- **Personal Reflections**