HPV Prevention and Control Board

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Prevention and control of HPV and HPV related cancers in Denmark: lessons learnt and the way forward

HPV surveillance

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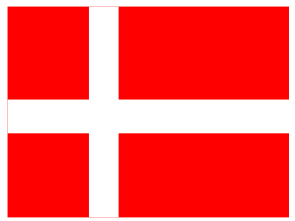
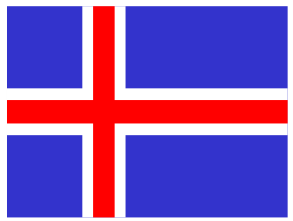
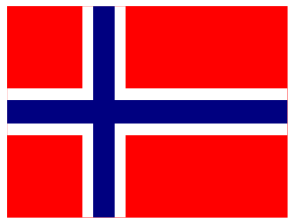
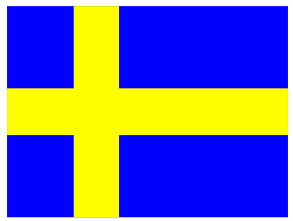
Conflicts of Interests

- Conference participation supported by SanofiPasteurMSD
- Lecture fees from SanofiPasteurMSD
- Some of the work presented today financed through unrestricted research grants from Merck

Objective of the presentation

A Nordic monitoring effort in

Denmark, Iceland, Norway and Sweden

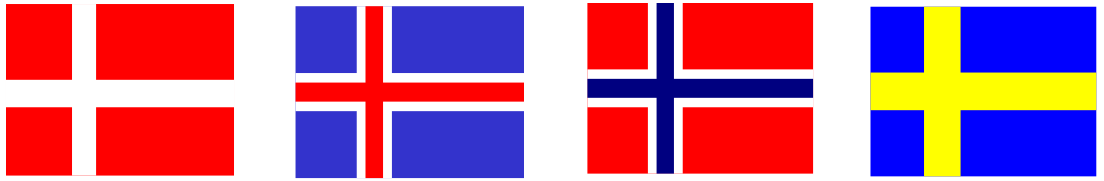





Background for follow-up studies in the Nordic region

- ✓ Every citizen in Denmark has a unique PIN called the CPR-number (10 digits with information on birth date and sex)
- ✓ The PIN is used universally in the Danish society, e.g. in health registries
- ✓ The same principle applies in the other Nordic countries

Registry	Data contained
Population registry	
Screening registry or health registries relevant for cervical cancer screening	
Pathology/cytology/histology registries	
Cancer registry	
Hospital discharge registry	
Data linkage: linked via the unique personal identification number (PIN)	

LTFU study



Denmark Iceland Norway Sweden

4 Nordic countries

(Denmark
Iceland
Norway
Sweden)

Long-term follow-up (LTFU) study

(extension of FUTURE II)

FUTURE 2

Data Analysis Overview

Effectiveness

- Per-protocol primary analysis*

Safety

- Deaths, cancers, hospitalizations, and other safety outcomes

Immunogenicity

- Vaccine type-specific antibody levels and seropositivity

*Subjects who received 3 doses of GARDASIL within 1 year, had no protocol violations, were seronegative and PCR-negative at baseline and PCR-negative through Month 7 to the appropriate HPV type(s), and consented to effectiveness follow-up.

VIP study … Vaccine Impact in Population

- Occurrence of HPV-related disease before and after introduction of GARDASIL
- Populations-based prevalence of HPV infection before and after introduction of GARDASIL
- Characterize women 18-45 years of age regarding a variety of lifestyle and other factors before and after introduction of GARDASIL
- Congenital anomalies in babies born to women inadvertently vaccinated with GARDASIL during pregnancy

Data collected in each of the 4 participating Nordic countries

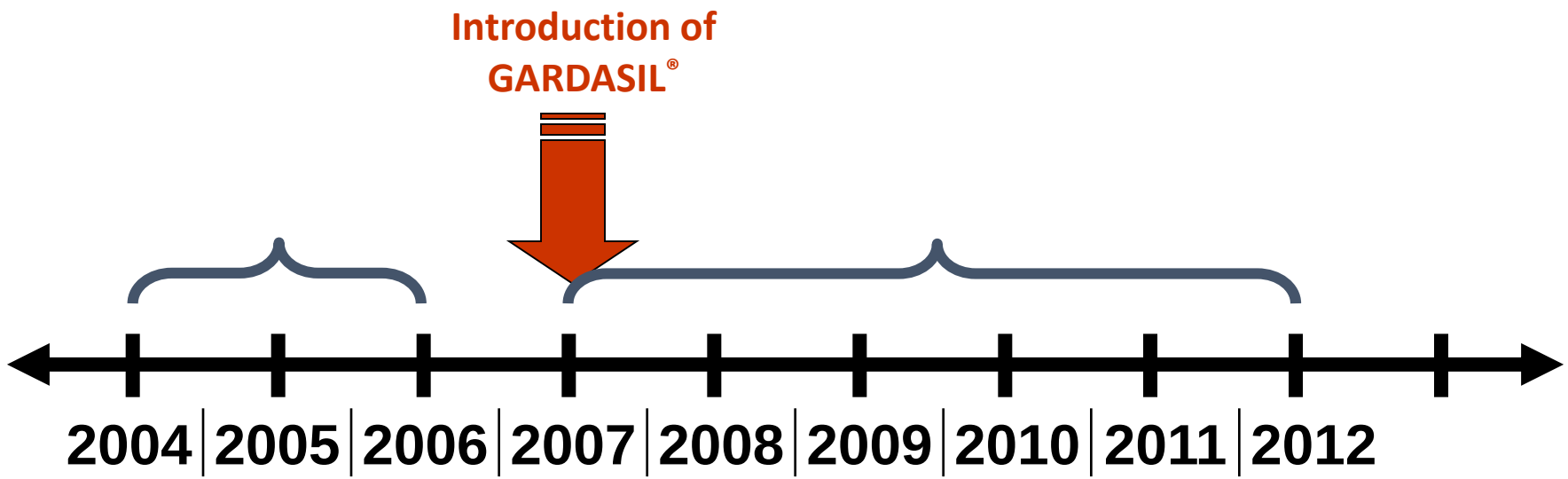
Pre-vaccine era:

- Incidence of HPV-related disease

Post-vaccine era:

- Incidence of HPV-related disease

Incidence of cervix, vaginal, and vulva cancer and their precursors



Data collected in each of the 4 participating Nordic countries

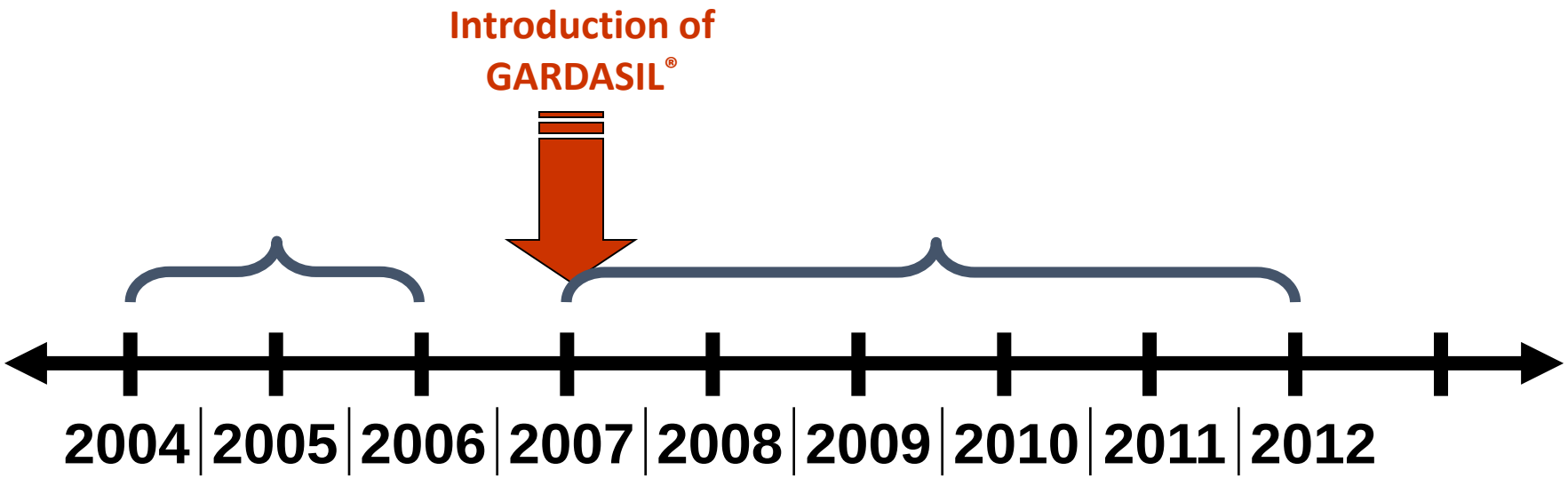
Pre-vaccine era:

- Incidence of HPV-related disease
- HPV type distribution in the general female population

Post-vaccine era:

- Incidence of HPV-related disease
- HPV type distribution in the general female population

2000 liquid-based cytologies for HPV detection (typing)



Data collected in each of the 4 participating Nordic countries

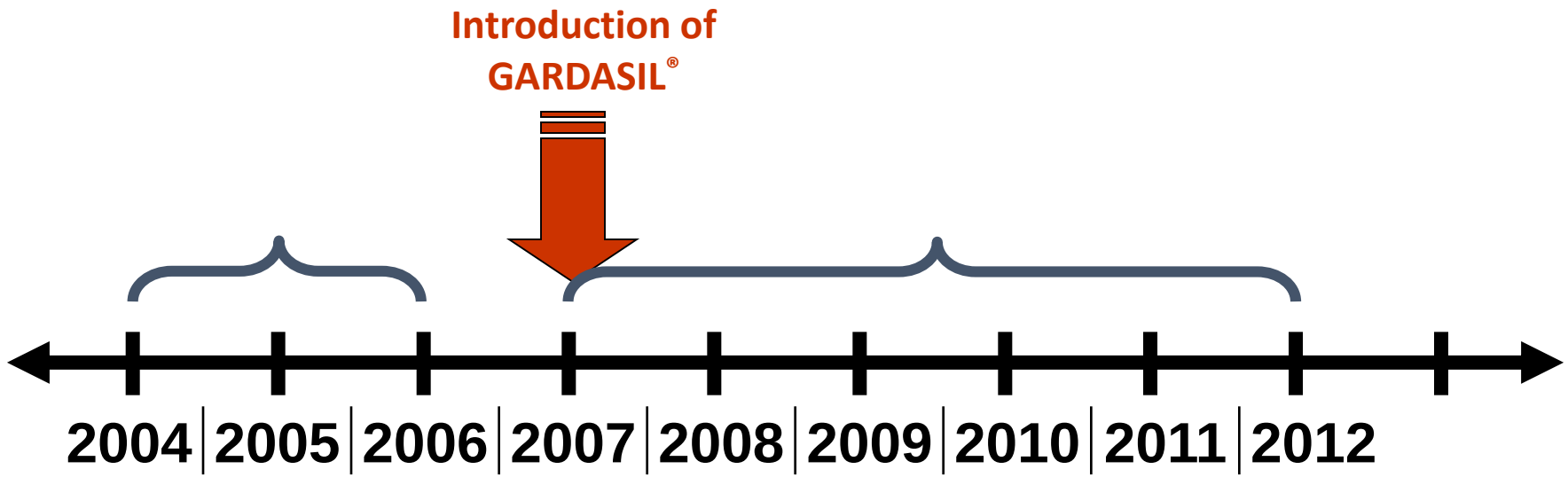
Pre-vaccine era:

- Incidence of HPV-related disease
- HPV type distribution in the general female population
- HPV type distribution in cervix cancer and CIN 2/3

Post-vaccine era:

- Incidence of HPV-related disease
- HPV type distribution in the general female population
- HPV type distribution in cervix cancer and CIN 2/3

300 CIN2/3 + 200 cervical cancers



Data collected in each of the 4 participating Nordic countries

Pre-vaccine era:

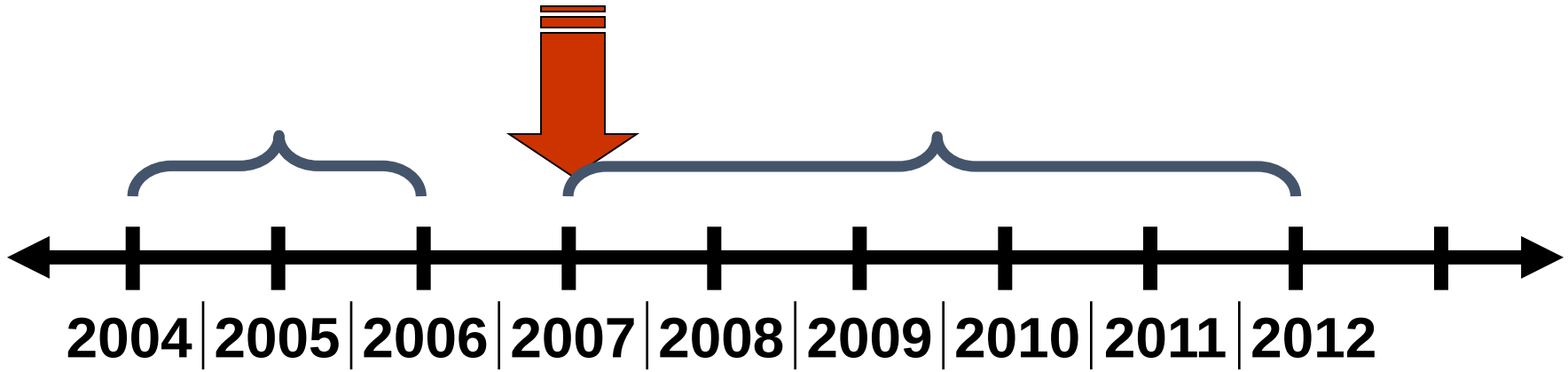
- Incidence of HPV-related disease
- HPV type distribution in the general female population
- HPV type distribution in cervix cancer and CIN 2/3
- Genital warts
- Sexual habits

Post-vaccine era:

- Incidence of HPV-related disease
- HPV type distribution in the general female population
- HPV type distribution in cervix cancer and CIN 2/3
- Genital warts
- Sexual habits

Introduction of GARDASIL®

Questionnaire survey: ~ 70,000 pre-vaccine era and ~ 50,000 post-vaccine era



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Post-vaccine era:

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- HPV type distribution in the general female population
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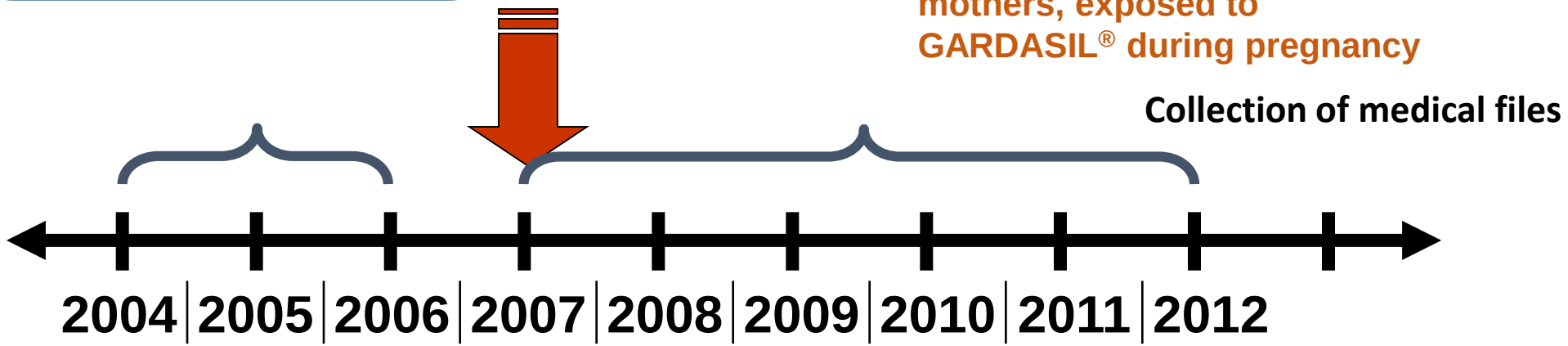
- Sexual habits

- Occurrence of congenital anomalies in babies born to mothers, exposed to GARDASIL® during pregnancy



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Post-vaccine era:

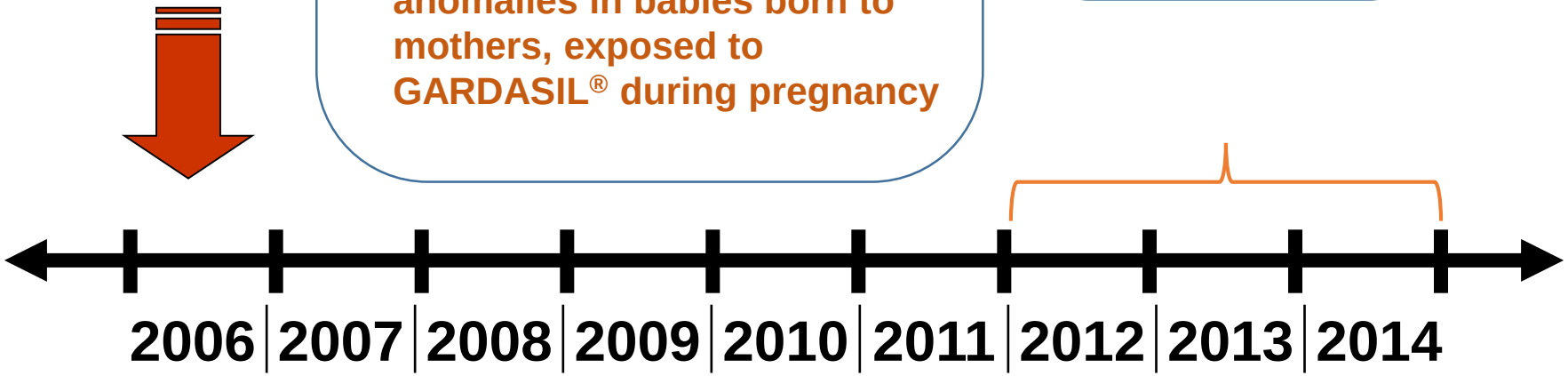
- Incidence of HPV-related disease
- HPV type distribution in the general female population
- HPV type distribution in cervix cancer and CIN 2/3
- Genital warts
- Sexual habits

- Occurrence of congenital anomalies in babies born to mothers, exposed to GARDASIL® during pregnancy

Post-vaccine era; extension

- Incidence of HPV-related disease

Introduction of GARDASIL®



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Summary

In Denmark, different initiatives of HPV monitoring are taking place

This involves ‘passive’ surveillance through registries, and ‘active’surveillance through e.g. questionnaire studies

This means that we can contribute with ‘real life’ data about the impact of HPV vaccination

Thank you for attention!