Clinical trial results:
Immunogenicity and Safety of the Influenza Vaccine (Split Virion, Inactivated), Northern Hemisphere 2010-2011 Formulation (Intramuscular Route)

Summary

Results information

Trial information

Trial identification

Additional study identifiers

Sponsors

Paediatric regulatory details

Results analysis stage

General information about the trial

Population of trial subjects

Subjects enrolled per country

Subjects enrolled per age group

Subject disposition

Recruitment

Pre-assignment

Period 1	

Arms	
Arm title	

Arm title	

Number of subjects in period 1		

Baseline characteristics

Reporting groups	

Reporting group values			

End points

End points reporting groups	

Primary: Geometric Mean Titers (GMTs) of Influenza Vaccine Antibodies Before and After Vaccination with Inactivated, Split-Virion Influenza Vaccine, Northern Hemisphere 2010-2011 Formulation by the Intramuscular Route

Statistical analyses

Primary: Geometric Mean Titers Ratios (GMTR) of Influenza Vaccine Antibodies After Vaccination with Inactivated, Split-Virion Influenza Vaccine, Northern Hemisphere 2010-2011 Formulation by the Intramuscular Route

End point values				

Statistical analyses

Primary: Percentage of Subjects Achieving a Titer of < 10 (1/dil) Against the Influenza Vaccine Antigens Before and After Vaccination with Inactivated, Split-Virion Influenza Vaccine, Northern Hemisphere 2010-2011 Formulation by the Intramuscular Route

End point values				

Statistical analyses

Primary: Percentage of Subjects with Seroprotection Against the Influenza Vaccine Antigens Before and After Vaccination with Inactivated, Split-Virion Influenza Vaccine, Northern Hemisphere 2010-2011 Formulation by the Intramuscular Route

End point values				

Statistical analyses

Primary: Percentage of Subjects with Seroconversion or Significant Increase Against the Influenza Vaccine Antigens Before and After Vaccination with Inactivated, Split-Virion Influenza Vaccine, Northern Hemisphere 2010-2011 Formulation by Intramuscular Route

End point values				

Statistical analyses

Primary: Percentage of Subjects with at Least One Reaction Corresponding to those Listed in the EMEA Note for Guidance Within 3 Days After Vaccination with Inactivated, Split-Virion Influenza Vaccine, Northern Hemisphere 2010-2011 Formulation (Intramuscular Route)

End point values				

Statistical analyses

Primary: Percentage of Subjects Reporting Solicited Injection-site or Systemic Reactions within 3 Days After Vaccination with Inactivated, Split-Virion Influenza Vaccine, Northern Hemisphere 2010-2011 Formulation by the Intramuscular Route	

End point values				

Statistical analyses

Primary: Percentage of Subjects Reporting Solicited Injection-site or Systemic Reactions More than 3 Days After Vaccination with Inactivated, Split-Virion Influenza Vaccine, Northern Hemisphere 2010-2011 Formulation by the Intramuscular Route

End point values				

Statistical analyses

Primary: Percentage of Subjects Reporting a Solicited Injection-site or Systemic Reactions Within 7 Days After Vaccination with Inactivated, Split-Virion Influenza Vaccine, Northern Hemisphere 2010-2011 Formulation by the Intramuscular Route

End point values				

Statistical analyses

Adverse events

Adverse events information	
Dictionary used	
Reporting groups	

Serious adverse events			

Non-serious adverse events			

More information

Substantial protocol amendments (globally)

Interruptions (globally)

Limitations and caveats