

*Transform Health Data into useful  
information*

# USE CASE

## Impact of safety measures

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# Use case : Use Case – Impact of safety measures



DEPAKINE®



Depakote®  
— divalproex sodium

## **Health watch : Impact of public Health Authorities safety measures on delivery behaviours**

Use of SODIUM VALPROATE within  
women in childbearing age

# Use Case – Impact of safety measures Sodium Valproate Context

- On the market since 1967, treating epilepsy and bipolar disorders
- Known harmful teratogenic effects that can result in foetus malformation



12th Decembre 2014

Letter to Health Professionals

Presentation of new data confirming a risk for in utero exposed children



26th May 2015

Press Conference & 2<sup>nd</sup> letter to HP

Announcement of new conditions of prescription and delivery : Valproate should no longer be prescribed to girls, female teenagers and women of childbearing age



November 2015

Fact Sheet

List of Alternative therapies



1st January 2016

Implementation of new conditions of prescription and delivery



23rd February 2016

Report by the IGAS

## Use Case – Impact of safety measures Objectives



- **Main objective**
  - Quantify the **impact of various health security measures**
- **Secondary objective**
  - Quantify the **influence of female patient's age** on the level of switch from VALPORATE to an alternative therapy



- **Constitution and tracking of cohort of patients treated with SODIUM VALPORATE**
  - Inclusion: 12th December 2013 to 11th December 2014
  - Tracking: 12 December 2014 to 1st May 2016

# Use Case – Impact of safety measures

## Inclusion criteria

### 0 Patients treated with VALPROATE

- Patients treated with VALPROATE between 12th Dec 2013 and 11th Dec 2014
- Filter on the age - 15 to 49 years old -



**12 892 female**  
patients



**13 786 male**  
patients

### 1 Quantity of Valproate delivered during the inclusion period

≥ 4 deliveries of Valproate between 12th Dec 2013 and 11th Dec 2014, with at least one of these after 11th Sep 2014 to be sure that these patients are still under treatment



### 2 No alternative therapy during the inclusion period

Exclusion of patients with at least one delivery of an alternative therapy, alone or in association with Valproate, between 12th Dec 2013 and 11th Dec 2014

**2 430 female**  
patientes  
(18,8 %)

**2 965 male**  
patients  
(21,5 %)

# Use Case – Impact of safety measures

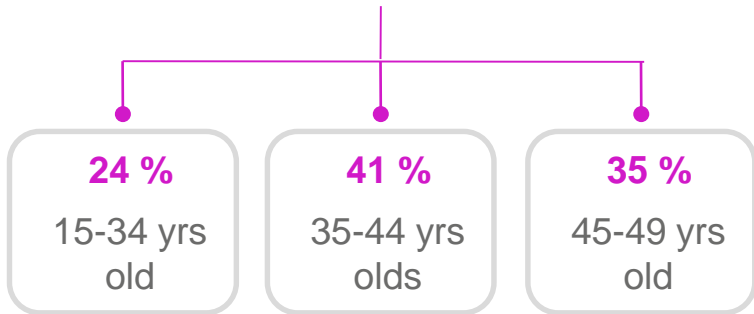
## Included population (1/2)



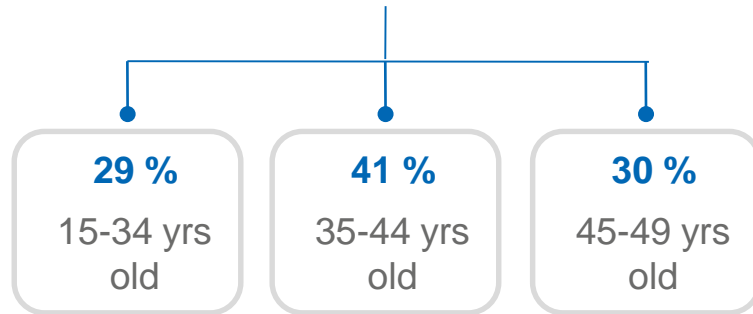
### Profile of included patients



**2 430** female  
(100,0 %)



**2 965** male  
(100,0 %)



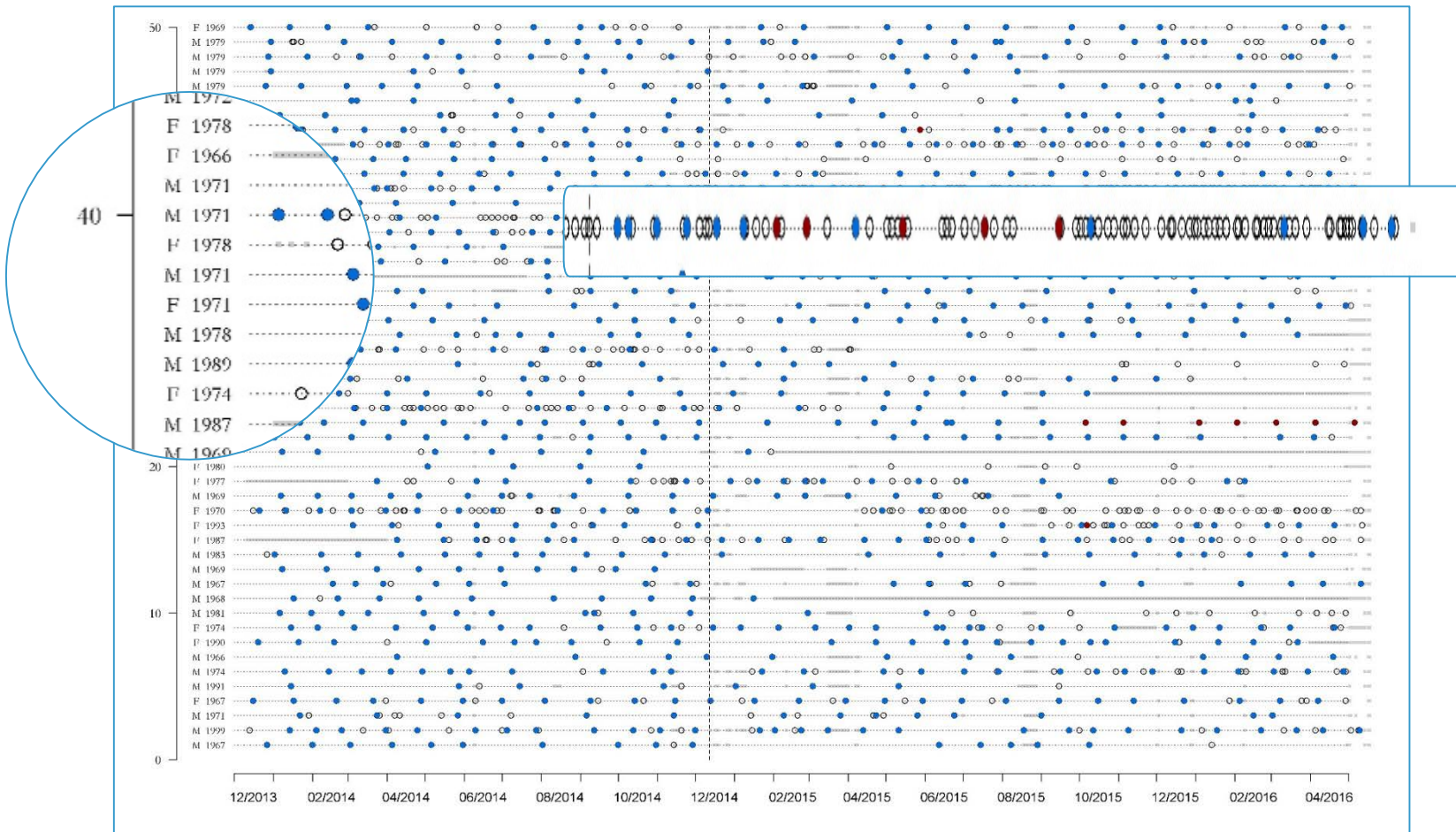
### Tracking of included patients

The follow-up period, starting 12th Dec 2014 till 1st May 2016, has been subdivided into 4 periods :

- Period 1: 12th Dec 2014 to 25th May 2015,
- Period 2: 26th May to 1st Nov 2015
- Period 3: 1st Nov to 31st Dec 2015
- Period 4: 1st Jan to 30th April 2016

# Use Case – Impact of safety measures Included population (2/2)

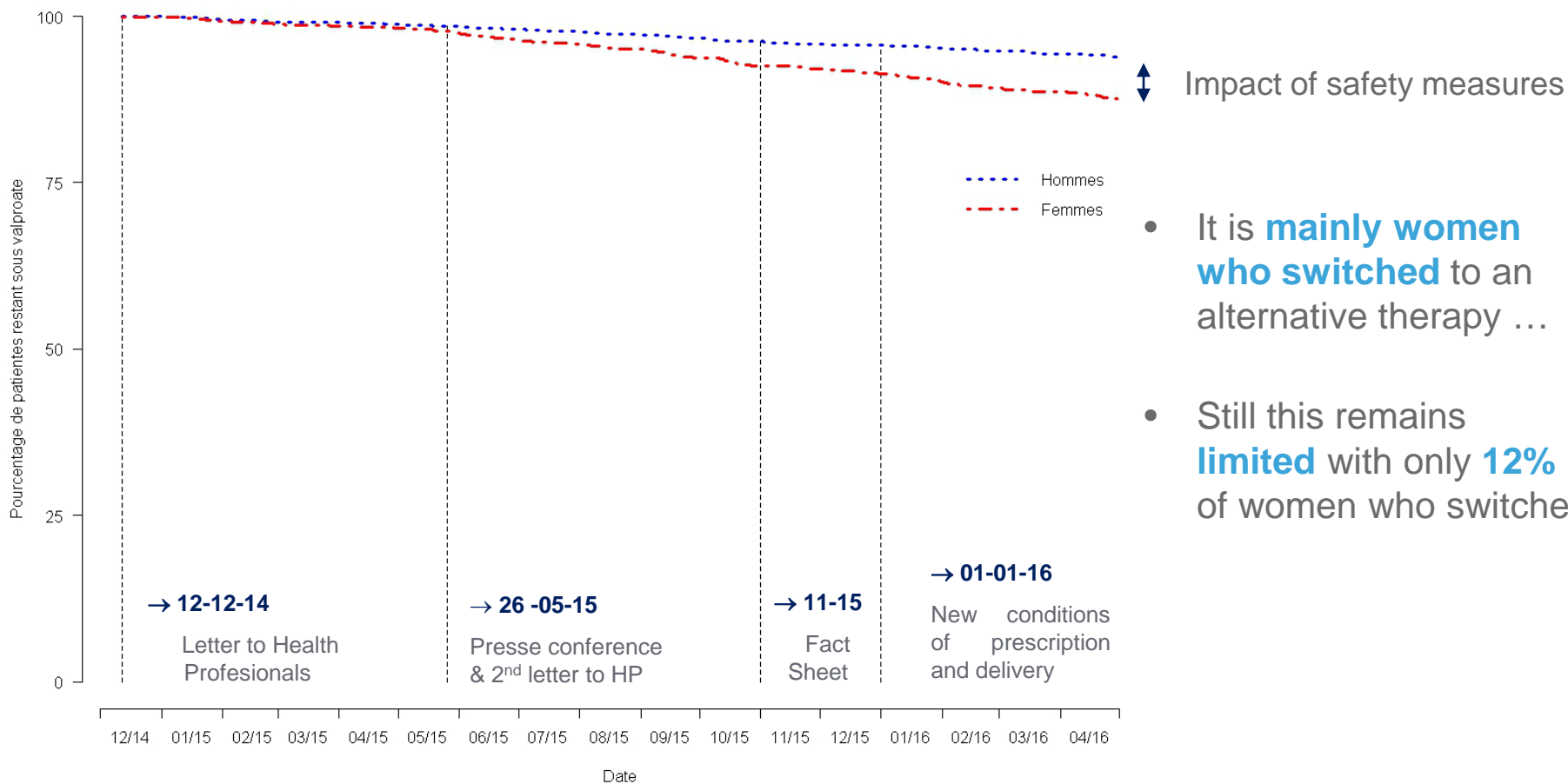
Graphic representation of longitudinal tracking of 50 patients treated with VALPROATE selected at random



# Use Case – Impact of safety measures

## Main results (1/2)

### Patients treated with VALPROATE switching to an alternative therapy

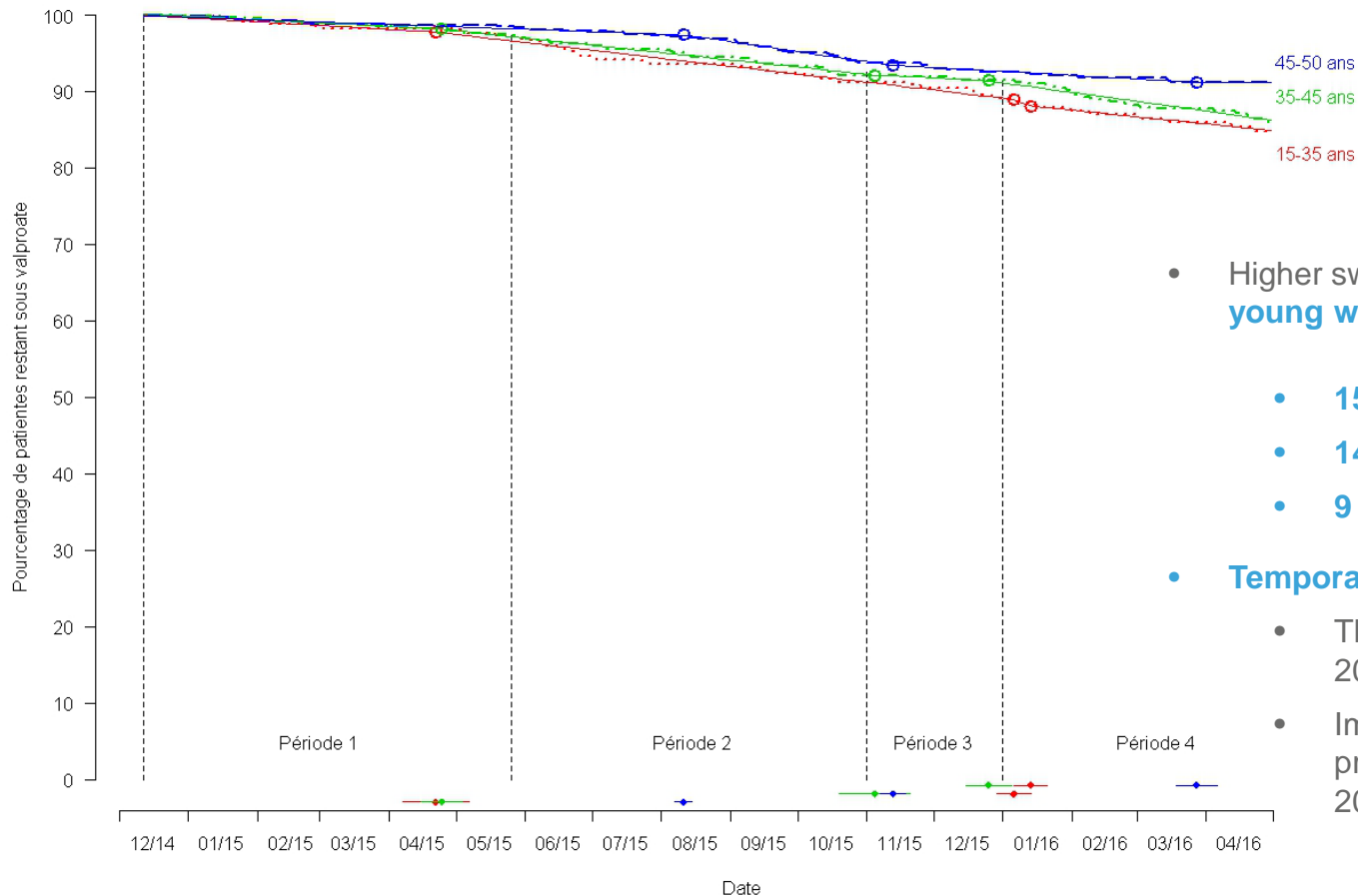




# Use Case – Impact of safety measures

## Main results (2/2)

### Patients treated with VALPROATE switching to an alternative therapy



- Higher switch to alternative therapies **within young women**
  - **15 %** of the 15-35 yrs old
  - **14 %** of the 35-45 yrs old
  - **9 %** of the 45-50 yrs old
- **Temporary accelerations** of switches after:
  - The announcement of 26th May 2015
  - Implementation of new conditions of prescription and delivery 1st Jan 2016