

# Conférence sur les Données en Vie Réelle

## Real World Evidence Conference

### AGENDA

**8-9 March 2022**

*Un événement organisé dans le cadre de la Présidence française  
du Conseil de l'Union Européenne.*

*An event organised in the framework of the French Presidency of the Council of the European Union.<sup>1</sup>*

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| <p><b>DAY 1: 8th March 2022</b></p> <p><b>Session 1</b></p> <p><b>9h30-13h00</b></p>   |   |
| <p><b>Sécurité des vaccins contre la Covid-19</b><br/>Safety of Covid-19 vaccines</p>  |   |
| <p><b>Moderators:</b></p> <ul style="list-style-type: none"> <li>- Laurence Baril, Head of Department Infectiology And Emerging Diseases, ANSM, France</li> <li>- Pierre Demolis, SAWP and Oncology WP member, Scientific Advisor to the DG, ANSM, France</li> </ul> |   |
| <p><b>9h30 – 9h40</b></p>  | <p><b>Introduction</b></p> <p><b><u>Speaker:</u> Christelle Ratignier Carbonneil, Director general, ANSM, France</b></p>  |
| <p><b>9h40 – 9h55</b></p>  | <p><b>Pharmacovigilance renforcée de la surveillance des vaccins contre la COVID-19 en France</b><br/>Reinforced pharmacovigilance of COVID-19 vaccines surveillance in France</p> <p><b><u>Speaker:</u> Mehdi Benkebil, Deputy Director, Surveillance division, ANSM, France</b></p> |

<sup>1</sup> Cet événement n'est pas organisé par le Gouvernement français. Il est cependant autorisé par celui-ci à utiliser l'emblème de la présidence française du Conseil de l'Union européenne.

This event is not organized by the French Government but is authorized to use the French Presidency of the Council of the European Union logo.

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| <p>9h55 –10h15</p>   | <p><b>Les centres régionaux de pharmacovigilance dans la surveillance des vaccins contre la COVID-19 en France</b><br/>The French Regional Pharmacovigilance Network in COVID-19 Vaccines safety monitoring</p> <p><b>Speaker:</b> Aurélie Granvullemin , Regional pharmacovigilance center Dijon, Vice-President of the French Network of Regional Pharmacovigilance Centres, France</p> |
| <p>10h15 –10h30</p>  | <p><b>Questions réponses</b><br/>Questions &amp; Answer</p>   |
| <p>10h30 –10h50</p>  | <p><b>Expérience d'un système de pharmacovigilance européen dans la surveillance des vaccins contre la COVID-19 , exemple norvégien</b><br/>An European pharmacovigilance system in the COVID-19 vaccines surveillance –the Norwegian experience</p> <p><b>Speaker:</b> Pernille Harg, Senior Advisor, Pharmacovigilance, Norwegian Medicines Agency, Norway</p>                          |
| <p>10h50 –11h00</p>  | <p><b>Questions réponses</b><br/>Questions &amp; Answer</p>   |
| <p>11h00 – 11h10</p> | <p><b>Pause –Break</b></p>  |

**Moderator: Mehdi Benkebil, Deputy Director Surveillance Division, ANSM, France**

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| <b>11h10 –11h40</b>  | <p><b>Etudes de pharmaco-épidémiologie :</b></p> <ul style="list-style-type: none"> <li>- <b>Myocardite et péricardite après la vaccination Covid-19</b></li> <li>- <b>Efficacité des vaccins anti-Covid-19</b></li> </ul> <p>Pharmaco-epidemiology studies:</p> <ul style="list-style-type: none"> <li>- Myocarditis and pericarditis after covid-19 vaccination</li> <li>- Efficacy of anti-Covid-19 vaccines</li> </ul> <p><b><u>Speaker:</u> Mahmoud Zureik, Director, EPI-PHARE Epidemiology Scientific Interest Group, France</b></p> |
| <b>11h40 –11h55</b>  | <p><b>Questions réponses</b><br/>Questions &amp; Answer</p>   |
| <b>11h55 –12h10</b>  | <p><b>Information et transparence</b><br/>Information and transparency</p> <p><b><u>Speaker:</u> Rose-Marie Tunier, Director, Communication and Information Division, ANSM, France</b></p>  |
| <b>12h10 –12h30</b>  | <p><b>Données en vie réelle et décision européenne</b><br/>Real World Data in the European decision</p> <p><b><u>Speaker:</u> Anette Kirstine Stark, PRAC member, Danish Medicines Agency, Denmark</b></p>  |
| <b>12h30 –12h45</b>  | <p><b>Questions réponses</b><br/>Questions &amp; Answer</p>   |
| <b>12h45 – 13h00</b> | <p><b>Conclusion Session 1</b></p>  |
| <b>13h00 – 14h00</b> | <p><b>Déjeuner – Lunch</b></p>  |

**DAY 1: 8th March 2022**

**Session 2**

14h00-17h30

**Initiatives des états membres dans les domaines des RWE**  
Initiatives of european member states in the field of safety RWE

**Moderators:**

- **Vincent Gazin, Deputy Director Europe and Innovation, ANSM, France**
- **Jean-Michel Race, CHMP member, ANSM, France**

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| 14h00 –14h10  | <b>Introduction</b>  |
| 14h10 –14h35  | <p><b>Cooperation entre les régulateurs et la recherche pour le Covid-19. Academia-regulator collaboration in covid-19</b></p> <p><b>Speaker: Anton Pottegård, Professor at University of Southern Denmark, Head of Research at the Hospital Pharmacy, Odense University Hospital, Denmark</b></p>                               |
| 14h35 –14h50  | <b>Questions réponses</b><br>Questions & Answer  |
| 14h50 – 15h15 | <p><b>Un réseau italien de soins de santé multi-bases de données: Le projet VALORE</b></p> <p>An Italian Distributed Multi-Database Healthcare Network:<br/>The VALORE Project</p> <p><b>Speaker: Gianluca Trifirò, Professor of Pharmacology - Department of Diagnostics and Public Health, University of Verona, Italy</b></p> |
| 15h15 –15h30  | <b>Questions réponses</b><br>Questions & Answer  |
| 15h30 – 15h40 | <b>Pause – Break</b>   |

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| 15h40 – 16h10 | <p><b>Opportunités et challenges pour générer des données de vie réelle à l'aide d'un modèle commun international de données</b><br/>Generating evidence using an international common data model</p> <p><b><u>Speaker:</u> Edward Burn, IDIAPJGol, Spain</b></p>   |
| 16h10 –16h25  | <p><b>Questions réponses</b><br/>Questions &amp; Answer</p>   |
| 16h25 – 16h55 | <p><b>Améliorer l'utilisation des preuves du monde réel à des fins réglementaires : DARWIN EU® et l'initiative de registre de l'EMA</b><br/>Enhancing use of real-world evidence for regulatory purposes: DARWIN EU® and the EMA registry initiative</p> <p><b><u>Speaker:</u> Xavier Kurz, Data Analytics and Method Task Force, EMA</b></p> |
| 16h55 –17h10  | <p><b>Questions réponses</b><br/>Questions &amp; Answer</p>   |
| 17h10 –17h30  | <p><b>Conclusion session 2</b></p>  |
| 17h30         | <p><b>Fin de la 1ère journée</b><br/>End of Day 1</p>   |

| <b>DAY 2 : 9th March 2022</b><br><b>Session 3</b><br><b>9h30-12h30</b>  |   |
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| <b>RWE au-delà de la pharmacovigilance et la pharmaco-épidémiologie</b><br>RWE beyond pharmacovigilance and pharmaco-epidemiology |   |
| <b>Moderator : Antoine Pariente, Professor of Medical Pharmacology at the University of Bordeaux, France</b>                      |   |
| 9h00 – 9h10   | Introduction  |
| 9h10 – 9h30   | <p><b>Utilisation des registres des maladies rares comme source de données en vie réelle, focus sur les travaux en cours des réseaux Européens de Référence Maladies Rares (ENRs)</b><br/> Utilization of rare disease registries as RWE resources, focusing on our ongoing work in the ERNs</p> <p><b><u>Speaker:</u> Franz Schaefer, Professor of Pediatrics, Head, Division of Pediatric Nephrology, Coordinator, European Reference Network for Rare Kidney Diseases, Center for Pediatrics and Adolescent Medicine , Heidelberg University Hospital, Germany</b></p> |
| 9h30 – 9h40   | <p><b>Questions réponses</b><br/> Questions &amp; Answer</p>  |
| 9h40 – 10h00  | <p><b>Présentation du Health Data Hub</b><br/> Health Data Hub presentation</p> <p><b><u>Speaker:</u> Roman Hossein Khonsari, Medical Director, Health Data Hub, France</b></p>   |
| 10h00 – 10h20   | <p><b>Présentation de Findata – Autorité chargée de l'autorisation des données sanitaires et sociales</b><br/> Presenting Findata – Health and Social Data Permit Authority in Finland</p> <p><b><u>Speaker:</u> Johanna Seppänen, Findata's Director, Finland</b></p>  |
| 10h20–10h30   | <p><b>Questions réponses</b><br/> Questions &amp; Answer</p>  |
| 10h30 – 10h40   | <b>Pause – Break</b>  |

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| <p><b>Moderators :</b></p> <ul style="list-style-type: none"> <li>- <b>Patrick Maison, Scientific Delegation, ANSM, France</b></li> <li>- <b>Corinne Kiger, Clinical Trial Referent, ANSM, France</b></li> </ul> |  |
| <p><b>10h40 –11h10</b></p>   | <p><b>Initiative européenne en matière de big data : rapport d'activité de l'HMA/EMA BDSG, DARWIN EU et projet pilote Raw Data.</b><br/>European big data initiative : HMA/EMA BDSG progress report including DARWIN EU and Raw Data pilot</p> <p><b><u>Speaker:</u> Jesper Kjaer, Director of Data Analytics Centre, Danish Medicines Agency, Co-chair of the BDSG, EMA</b></p> |
| <p><b>11h10 –11h35</b></p>   | <p><b>Les données de vie réelle dans le développement des médicaments</b><br/>Real world evidence in clinical developments</p> <p><b><u>Speaker:</u> Peter Mol, University Medical Center Groningen, Senior assessor CBG-MEB, SAWP vice-chair, The Netherlands</b></p>   |
| <p><b>11h35 –11h45</b></p>   | <p><b>Questions réponses</b><br/>Questions &amp; Answer</p>  |
| <p><b>11h45 –12h00</b></p>   | <p><b>Les registres et les essais cliniques en pédiatrie</b><br/>Registries and clinical trials in children</p> <p><b><u>Speaker:</u> Sylvie Benchetrit, Pediatric referent, ANSM, France</b></p>  |
| <p><b>12h00 –12h20</b></p>   | <p><b>L'utilisation des données de vie réelle en oncologie pédiatrique</b><br/>RWE in pediatric oncology</p> <p><b><u>Speaker:</u> Gilles Vassal, Pediatric Oncologist, Professor of oncology, Gustave Roussy, France</b></p>  |
| <p><b>12h20 –12h30</b></p>   | <p><b>Questions réponses</b><br/>Questions &amp; Answer</p>  |

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| <p><b>Round Table</b><br/>12h30 -13h30</p>  |   |
| <p><b><u>Moderators:</u></b></p> <ul style="list-style-type: none"> <li>- <b>Christelle Ratignier-Carbonneil, General Director, ANSM, France</b></li> <li>- <b>Patrick Maison, Scientific Delegation, ANSM, France</b></li> </ul> |   |
| <p>12h30 – 13h30</p>  | <p><b><u>Speakers:</u></b></p> <ul style="list-style-type: none"> <li>- <b>Virginie Hivert, Therapeutic Development Director<br/>EURORDIS - Rare Diseases Europe</b></li> <li>- <b>Roman Hossein Khonsari, Medical Director, Health Data Hub,<br/>France</b></li> <li>- <b>Jesper Kjaer, Director of Data Analytics Centre, Danish<br/>Medicines Agency, Co-chair of the BDSG, EMA</b></li> <li>- <b>Gianluca Trifirò, Professor of Pharmacology - Department of<br/>Diagnostics and Public Health, University of Verona, Italy</b></li> <li>- <b>Mahmoud Zureik, Director, EPI-PHARE Epidemiology<br/>Scientific Interest Group, France</b></li> </ul> |
| <p>13h30</p>  | <p><b>Fin de la RWE Conference<br/>End of the RWE Conference</b></p>  |