DIA VIRTUAL MEETING

Workshop for Advancing Patient Science

Steps for Patient Centricity & PROs

03-04 December 2020

PROGRAMME ADVISORS

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Key Topics

- Value and Future of PROs in Clinical Trials
- Patient Centric Clinical Trials
- PROs in Regulatory Decision Making
- EMA, FDA and EUnetHTA perspectives on PROs
- Adoption of PROs in Clinical Practice
- Patient-focused label for the future
- Advancing Patient Safety through Digital Platforms

Overview

The Advancing Patient Science Workshop will reflect and discuss how to better incorporate patients' input and contribution throughout the medicines lifecycle.

Firstly, we will reflect on how to Advance Patient Centricity, starting with a discussion on how to build Patient centric Clinical Trials to maximize adoption, followed by how to create a true Patient-focused label in the future and which are the main challenges to making this a reality.

Next, we will briefly reflect on how to Advance Patient Safety, and the importance of Digital Platforms to achieve this and for enhancing HCP to Patient Dialogue.

Finally, the last day will be dedicated to Patient-reported outcomes (PROs). With the increasing awareness of their importance, PROs have recently been the subject of many discussions, particularly on what concerns its definition, collection, usage and inclusion in regulatory decision making. However, many questions prevail and are in need of further discussion: How to best integrate them in Regulatory decision making? What are currently the main challenges with PROs and how to best integrate them in clinical practice?

On this Workshop, we will gather the view of different stakeholders on the different subjects and further discuss how can we effectively advance Patient Science.

Who should attend:

Professionals involved in:

- Clinical Development
- Clinical Trial Design
- Data Sharing and Usage
- Data Analysis
- Data Science
- Decentralised Clinical Trials
- Regulatory Decision Making
- Regulatory Science
- Regulatory Innovation
- Study Design
- Development Programme Managers
- Patient Engagement
- Patient Advocacy

About DIA

DIA is the global connector in the life sciences product development process. Our association of thousands of members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

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DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China. For more information, visit www.DIAglobal.org or call DIA: +41 61 225 51 51.

DAY ONE | THURSDAY, 03 DECEMBER 2020

PART 1: ADVANCING PATIENT CENTRICITY

14:00 LOG-IN

14:10 WELCOME AND INTRODUCTION TO THE WORKSHOP

Sara Torgal, Scientific Programmes Manager, DIA, Switzerland

14:30 SESSION 1

A FLEXIBLE APPROACH TO BUILDING PATIENT CENTRIC CLINICAL TRIALS: NAVIGATING THE CHALLENGES TO MAXIMIZE ADOPTION

Session Chair:
Scott Askin, Global Program Regulatory Director, Regulatory Affairs Innovation, Novartis, Switzerland

DCT State of Play
Josh Rose, Head of Virtual Trial Solutions, IQVIA, USA

Healthcare perspective and challenges
Evelien Rooke, Senior Neurology Registrar & Clinical Research Fellow, University of Dundee, UK

Patient perspective and challenges
Helen Matthews, Deputy CEO, The Cure Parkinson's Trust, UK

Going Home
Megan Heath, Head of Clinical Study Units Europe Region, Sanofi, UK

Panel discussion with Q&A, with the additional participation of:
Isaac Rodriguez-Chavez, Former Lead Officer for Decentralized Clinical Trials at FDA, USA

15:50 BREAK

16:05 SESSION 2

PATIENT-FOCUSED LABEL FOR THE FUTURE: HOT AIR OR REAL OPPORTUNITIES?

Session Chair:
Aimad Torqui, Director Global Regulatory Policy, MSD, Netherlands

The Patient-Focused Label: Setting the scene
Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK

ePI Principles
Elizabeth Scanlan, Scientific Administrator, Stakeholders and Communication Division, European Medicines Agency, EU

Panel discussion with Q&A, with the additional participation of:
Sabrina Conti, Policy and Regulatory Coordinator, Medicines for Europe, Belgium
Deborah Bebbington, Vice President, Head Labeling, Bayer, UK
César Hernández García, Head of Department, Department of Medicines for Human Use, Spanish Agency for Medicines and Medical Devices, Spain

17:05 BREAK

PART 2: ADVANCING PATIENT SAFETY

17:20 SESSION 3

ADVANCING PATIENT SAFETY AND HCP TO PATIENT DIALOGUE VIA DIGITAL PLATFORMS

Session Chair:
Mark Perrott, Head of Development, Huron Life Sciences, UK

Initiating and establishing a digital aRMM programme
Stephany Jones, F. Hoffmann-La Roche AG, Switzerland

The potential for digital tools to achieve the risk management needs of advanced therapeutics
Meredith Smith, Director, Risk Management, Global Drug Safety, Alexion Pharmaceuticals, US

Future opportunities in digital customer interactions: beyond communication to engagement
Fabio Lievano, VP, Safety Science - Medical Safety Evaluation, Abbvie Pharmaceuticals, US

Panel discussion with Q&A

18:20 WRAP-UP

18:40 NETWORKING ACTIVITY

19:30 END OF DAY ONE

PART 3: ADVANCING PATIENT-REPORTED OUTCOMES

14:00 WELCOME AND INTRODUCTION

Sara Torgal, Scientific Programmes Manager, DIA, Switzerland

14:15 SESSION 4

PROS IN REGULATORY DECISION MAKING

Session Chair:
Nathalie Bere, Patient Engagement, European Medicines Agency, EU

PROs can be used to capture the everyday experience, outside the clinician's office, and the effects of a treatment on their daily activities. Furthermore, in some cases, PROs enable the measurement of important health status information that cannot yet be detected by other measures, such as pain. According to FDA, "for regulatory purposes, high-quality information from PRO measures can provide valuable evidence for benefit-risk assessments and can be used in labelling to communicate the effect of a treatment on patients' symptoms, functioning and quality of life."

In this session, we will hear from EMA, FDA and HTA bodies representatives about the learnings, current challenges, and future goals for the inclusion of PROs in regulatory decision making.

Learnings from the FDA Journey to Include PROs
Michelle Campbell, Senior Clinical Analyst for Stakeholder Engagement, ON, OND, CDER, FDA, US

PROs in Regulatory Decision Making: the perspective from EMA
Francesco Pignatti, Head of Oncology and Hematology, European Medicines Agency, EU

PROs in Regulatory Decision Making: the HTA perspective
Beate Wieseler, Head of Department, Institute for Quality and Efficiency in Health Care (IQWiG), Germany

Panel discussion with Q&A, with the additional participation of:
Anthony Humphreys, Head of the Regulatory Science and Innovation Task Force, European Medicines Agency, EU

15:15 BREAK

15:30 SESSION 5

MULTI-STAKEHOLDER PERSPECTIVES ON THE VALUE AND FUTURE OF PATIENT-REPORTED OUTCOMES IN CLINICAL TRIALS

Session Chair:
Thomas Morel, Director, Patient-Centred Outcomes Research, UCB Biopharma, Belgium

The use of patient-reported outcomes to harness the patient voice in clinical trials is gaining momentum. Do healthcare stakeholders' views converge on the value of PROs?

PROs from a Patient Perspective
Roger Wilson, Patient Representative, UK

PROs from a Trialist Perspective
Melanie Calvert, Director of the Centre for PROs Research, University of Birmingham, UK

PROs from a Regulatory Science Perspective
Daniel O'Connor, Medical Assessor, Medicines and Healthcare products Regulatory Agency (MHRA), UK

PROs from a Regulatory Science Perspective - focus on Neurology
Pavel Balabanov, Head of Therapies for Neurological and Psychiatric Disorders, European Medicines Agency, EU

PROs from an HTA Perspective
Caridad Pontes, Head, Pharmacotherapeutic Harmonization, Catalan Health System, Spain

PROs from the Pharmaceutical Industry Perspective
Thomas Keeley, Director, Patient Centred Outcomes, GlaxoSmithKline, UK

PROs from an Outcomes Measurement Perspective
Antoine Regnault, Global Lead Statistics, Modus Outcomes, France

Panel discussion with Q&A

17:05 BREAK

DAY TWO | FRIDAY, 04 DECEMBER 2020

17:20 SESSION 6

DRIVING THE ADOPTION OF PROS IN CLINICAL PRACTICE

Session Chair:
Tom Willgoss, Head of Late Stage Portfolio and Commercialisation, Patient Centered Outcomes Research, Product Development, Roche Pharmaceuticals, UK

In this session, we will take a look at what the future should and could look like for PROs: How do we ensure higher integration of PROs in routine clinical practice and that these measures become routine and part of the standard of care? How can PRO data be integrated seamlessly into the clinical workflow? How do we contextualise data collection to patients and ensure they understand the value and interact with the data (the right questions, for the right patient, at the right time)?

The status of Health Outcomes and Transparency across Europe – why we should measure PROs and the Value this creates for all Stakeholders in the Healthcare Ecosystem
Christina Åkerman, Senior Institute Associate, Institute for Strategy and Competitiveness, Harvard Business School & Associate Faculty Dell Medical School University of Texas at Austin & former ICHOM president, US

Levelling PROs with Clinical Outcomes – integrating patient-generated data with routine clinical data and leveraging at the point of care
Matthias Rose, Chair of the Department of Psychosomatic Medicine, Charité – Universitätsmedizin Berlin, Germany

PROs in clinical practice from the patient perspective – what drives patient adoption and what value do they provide to patients?
Avril Daly, CEO Retina International, VP EURORDIS, Ireland
Salvatore Leone, Chairman European Federation of Chrohn's and Ulcerative Colitis Federations

Panel discussion with Q&A

18:30 WRAP-UP

Sara Torgal, Scientific Programmes Manager, DIA, Switzerland

Thomas Morel, Director, Global Patient-Centred Outcomes Research, UCB & Research Fellow, KU Leuven, Belgium

Thomas Metcalfe, Data Policy Leader, Personalised Healthcare, F. Hoffmann-La Roche, Switzerland

18:45 END OF THE WORKSHOP

Disclosure Policy

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

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