ephmra
excellence - community - standards

# Welcome to the June 2022 News

## Delivering the membership benefits to you

Ensuring you know what's on offer

## In-person and Online - for 2022-2023

**Updates inside:**

Board | Events | Committee | Ethics

# Welcome to the EPHMRA June 2022 News

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## Member News

Agency Members can include one piece of News for free: 50 words max (increased from 30 words) plus photo/logo.

## Member Articles

In addition we encourage companies to submit articles for publication – these can be on any topic you think the EPHMRA audience would find interesting. There is no charge for these articles but it's an offer only available to Agency Members of EPHMRA.

Each article can be one A4 page long (full page) and supplied ready formatted as follows:

| | |
|---|---|
| No bleed | 297mm x 210mm |
| With bleed | 307mm x 220mm |
| Type Area | 277mm x 190mm |

Resolution/Artwork - If using photoshop or software dependent on resolution please ensure that it is set at the correct size and that the resolution is set to no less than 300dpi. Finished artwork needs to be supplied in CMYK with embedded fonts, or text should be converted to outlines/paths and supplied as an EPS. Print quality PDF files are also acceptable. PLEASE NOTE: We cannot be held responsible for any misprint, if fonts are not embedded/converted and the file is not in CMYK.

System - Apple Mac

Programmes - Quark Xpress, Adobe Illustrator, Freehand, Adobe Photoshop

File formats - Graphics should be supplied (CMYK) in the following formats EPS, TIF, JPEGS and Print Quality PDF files.

## Copy Deadline

For the September 2022 News -
Copy deadline is 15 July 2022
Send to generalmanager@ephmra.org
www.ephmra.org

## Get in touch

If you have any enquiries, suggestions or feedback just email us: Bernadette Rogers, General Manager Email: generalmanager@ephmra.org

Meet the
EPHMRA Board

# Who are your representatives on the board?

**Karsten Trautmann**
**Merck KGaA**
Board Industry Member
President

**Thomas Hein**
**Thermo Fisher Scientific**
Board Industry Member
Past President

**Gabi Gross**
**Thermo Fisher Scientific**
Board Industry Member

**Richard Head**
**Research Partnership**
Board Agency Member

**Xander Raijmakers**
**Eli Lilly Nederland BV**
Board Industry Member

**Nicola Friend**
**AstraZeneca**
Board Industry Member

**Richard Hinde**
**Norgine**
Board Industry Member

**Stephen Potts**
**Purdie Pascoe**
Board Agency Member

**Marcel Slavenburg**
**SKIM**
Board Agency Member

**Carolyn Chamberlain**
**Blueprint Partnership**
Board Agency Member

**Amr Khalil**
**Ripple International**
Board Agency Member

# MR Excellence Awards 2022

## Making a Business Impact
**(sponsored by Adelphi)**

Winners:

Christopher Recaldin, Associate Director at Branding Science
& Kim Kallsen, Global Head of Patient and Site Engagement at Boehringer Ingelheim

Developing a clinical trial engagement strategy to make Boehringer Ingelheim the sponsor of choice for sites and patients.

## Future Leaders – Case Study Award
**(sponsored by Blueprint Partnership)**

Sarah Cooper, Senior Research Executive, Branding Science Group

Focusing in on rare disease drug development: 3 case studies at different stages of the drug life cycle.

## Innovative Approach
**(sponsored by AplusA)**

Kate Melbourne, Director, Insights & Strategy and Dominique Cummuta, Manager, Insights & Strategy, BioVid

Novel Approaches to Engagement: Finding and Leveraging the Patient Voice.

**The award winning presentations took place on 8 June – see the EPHMRA website for the recordings – log in then webinars**

**Huge thanks to our Judges who, in 2022, freely gave their time to judge the Award submissions.**

- Aline Abravanel - Genactis
- Carolyn Chamberlain - Blueprint Partnership
- Charles Chaine - AplusA
- Chris Lewis-Deboos - Strategic North
- Daniel Guerin - AplusA
- Hannah Mann - Day One Strategy
- Kelly Warth - Instar Research
- Niclas Holmes - Brains and Cheek
- Rachel Pughe - Adelphi Group
- Rob Seebold - Buzzback
- Robert Cortese - Elma Research
- Vrinda Deval - Glocalmindv

# Upcoming Events

**13 September 3-4pm UK**

## Expert Panel Focus on Conjoint


Convenor:
Alexander Rummel, Aurum Research and LDC member

**Speakers:**

1. Richard Goosey, Head of Analytics, Research Partnership
2. Remco Don, Director, SKIM
3. Dawn Palace, Senior VP, Adelphi
4. Joe Jones, Data Scientist, Adelphi

We will have four major topics for discussion:

- Building virtual patients with conjoint
- Conjoint designs for small sample sizes, i.e., for rare diseases or market access work
- Conjoint used in pricing research
- Expectations and limitations of conjoint designs

**15 September 3-4pm UK**

## Early Commercial Forecasting & Strategy


**Speakers:**

1. Eric Holzinger, Founder & Director
2. Anne Ollivier, groupH

This 60 minute webinar will describe the underlying philosophy and the basic modules required to successfully complete an early stage commercial assessment.

We will

- take the participants through various archetypes of situations and describe the differences in approach
- discuss the pros and cons of various forecasting methodologies and frameworks in light of different opportunities
- understand the differences of going through this process in a smaller biotech or in a larger pharma organisation.

There is no one-size-fits-all, every project is unique in its way and many of the tools we are using or developing are too. Optimise value creation for your organization and adopt a value based approach.

## 2022 AsiaPac Conference

EPHMRA is delighted to announce we will be holding an AsiaPac focussed online event in 2022 – this conference will be a deep dive into topics relevant to healthcare market research and business intelligence in the region.

Dates to Note The conference will take place on 18 October 2022, starting at 8am UK time (that's 17.00hrs Japan time) to 12 noon UK time (21.00hrs Japan time).

It is great to announce our Convening Group – all with extensive experience in the region.

- Otto Tsang, Director, Regional Insights & Analytics, APAC, Healthcare Business of Merck Biopharma
- Marc Yates, Senior Director, Asia Pacific & Emerging Markets, Research Partnership
- Pieter De Richter, Head of APAC/MENA Syndicated Real World Evidence Healthcare, Ipsos Kuala Lumpur
- Stephen Potts, Director, Purdie Pascoe

We are currently developing the programme – more news soon.

## A BIG thank you to our Convenors and members of the Programme Committee -

**Elizabeth Kehler**
Managing Director
Adelphi Research

**Georgie Cooper**
Partner
Basis Health

**Carolyn Chamberlain**
Commercial Director
Blueprint Partnership

**Erik Holzinger**
Founder & Director
groupH

**Roy Rogers**
Director
Research Partnership

**Sarah Phillips**
VP, Practice Lead,
IQVIA

**Tracy Machado**
Director
Elma Research

**Stephen Potts**
Director
Purdie Pascoe

**Amr Khalil**
Managing Director
Ripple International

## 2022 Online Conference

Over 400 delegates registered for the 3 day event – many companies taking advantage of the flexible unlimited tickets on offer.

There were over 35 speakers at the events with a wide range of topics covered and there was a lot of discussion at the end of each paper.

We are now busy preparing the:

- Paper recordings – editing and tidying up
- Paper write ups – for our post conference news

We will let you know when the recordings are available on our vimeo channel.



## 2023 CONFERENCE

## 20 – 22 June 2022

### To be held at the Flanders Meeting and Convention Centre in Antwerp.

This will be our first in-person conference since 2019 as the 2020 - 2022 June Conferences were held online. We will be announcing the Call for Papers - look out for the email!

## Events Update – April - June


## UK One Day meeting – in -person on 26 April

Just over two years since the last EPHMRA UK One Day Meeting in February 2020, over 85 delegates gathered in London at one of the first industry face-to-face events since the lifting of Covid-19 restrictions. The meeting convenors had rafted a programme to look at future trends given that many fundamental changes that have affected pharmaceutical market research as a result of the pandemic. With plenty of opportunity for everybody to share their thoughts and experiences, the meeting offered a lively forum for debate and discussion on the future of our industry.

The venue was 30 Euston Square invcentral London and this proved to be a spacious and flexible meeting venue.

### A BIG Thank you to our meeting Convenors

Right at the start of the meeting all the delegates were thanked for attending. The hard work behind the scenes to develop and shape the agenda was evident and the Convenors were thanked for their commitment and a huge dose of enthusiasm!

Alex Marriott
Lumanity

Anna Garofalo
Janssen

Gayle Hughes
Pfizer

John Grime
Strategic North

Full report is available on the web site at www.ephmra.org – log in

## 11th Germany Online meeting – 12 and 13 May

Our convenors have reviewed market trends and feedback from the 2021 Germany meeting as well as looking at the industry landscape and challenges faced amongst our colleagues.

The meeting was convened by:

Katja Birke
Managing Director -
Produkt +Markt

Yannick Rieder
Manager Market Research & CI
- Janssen-Cilag GmbH

Barbara Lang
Managing Director
Point Blank Research & Consultancy

The great topics addressed were:

- Foresight. Trends. Pharma. Foresight and trend research in pharma companies.
- Beyond Social Listening: Supporting Patient-focused Drug Development with Online Patient Experience Research.
- Climbing up the Social Insights Ladder: How to iteratively explore multifaceted diseases and their discursive environment in social media
- Unboxing insights along the Customer Journey
- Behavioural audit: How post-hoc analysis can uncover hidden drivers of behaviour in existing data.

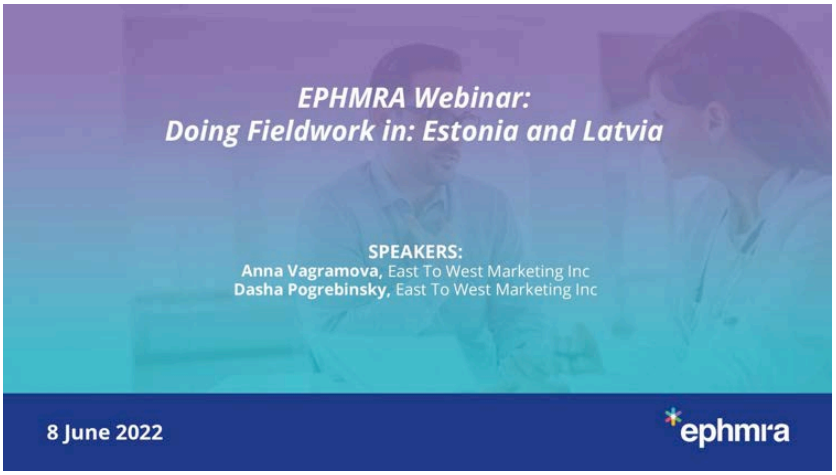
The meeting recordings are available on the EPHMRA web site – log in – One Day Meetings

## June Webinars

Webinar: Accessing markets, key influencers and respondents.  What you need to know – Estonia and Latvia – 8 June

This webinar focussed on giving you some hints and tips about 'Doing market research' in these markets and covered the healthcare system, sampling, accessing respondents, key factors to consider.

Speaker: Anna Vagramova, East to West Marketing Research



## May Events:

### Panel Discussion - The Future of Work:Life Balance from the LDC – 5 May


The COVID pandemic brought many changes in people's lives, big or small. One of the changes and challenges many people, in both their personal and professional lives are dealing with is the balance between work and life. Our session will focus on these changes and the impact they have on people and organisations.

How do people and organisations deal with questions around:

- Work effectiveness and productivity;
- Different management and work styles (office - hybrid - remote)
- Work-life balance, diversity, equality and inclusivity.

What is the impact of these changes on:

- Recruitment and retention with regard to business continuation;
  Impact on different generation (boomers, GenX, GenZ, GenNext)
- Personal effectiveness and well-being;
  Isolation vs getting work done, team feeling, etc.

Panellists:

LDC: Lara Lucchese, Bristol Myers Squibb and Marcel Slavenburg, SKIM

Anja de Caux, Professional Co-Active Coach at ZS Associates

India Williams, Associate Director, Market Research at Bristol Myers Squibb

Caroline Saner, Developing Talent at Backbase

### Webinar: Accessing markets, key influencers and respondents. What you need to know – Sweden and Switzerland - 17 May

This webinar focussed on giving you some hints and tips about 'Doing market research' in these markets and covered the healthcare system, sampling, accessing respondents, key factors to consider.

Speakers: Alexandra Benoist and Olga Ostrovska from QQFS.


### Webinar: Harnessing the Power of Semiotics to Decode Weight Loss – 3 May

Speaker: Rachel Lawes – Semiotics Consultant from Lawes Consulting

This webinar from semiotics thought leader and expert Rachel Lawes will focus on a case study: How to sell weight loss using semiotics. Comparison of the marketing communications around contrasting WL brands and solutions reveals their strengths and weaknesses. While the global obesity crisis worsens, the reasons why people find WL difficult, the way they think about their problem and the kinds of WL solutions they respond to are all culturally specific. Brands do better when, instead of simply trying to differentiate themselves from other brands, they additionally pay attention to the local, cultural issues that influence people's ability to recognise, take up and use WL solutions. This case study will illuminate the added value semiotics can bring to understanding the patients' complex physical and emotion relationship with their health and weight.

Rachel will also look at: What is semiotics? A short and handy guide to the two stages of semiotics: bottom-up and top-down. Bottom-up is about decoding signs and symbols and reveals the meanings conveyed by ads and packaging. Top-down is about decoding society – revealing the past, present and future meanings of ideas such as "obesity", "body positivity" and "working on" one's health.

So, what are the FAQs for researchers? When in the research cycle should you use semiotics? How are semiotic findings validated? Can anyone do semiotics and how would a researcher get started?

# Ethics Update

## June Ethics News

This is a members only resource and gives a round up of key developments which we in healthcare market research need to take note of.


## Upcoming projects to Support the Membership

### 1. Guidelines of Publishing Market Research

- planning at survey initiation

### 2. FMV survey amongst industry members

- participating industry member companies will receive a benchmarking report (all anonymised)
- summary report issued to the membership. Aiming for Q4 2022.

### 3. Consent Forms

- producing templates for the 5 main EU countries

## Suppliers Directory | EPHMRA

If you are working in healthcare business intelligence / market research and would like to advertise your services this is the Directory for you and an opportunity to connect. EPHMRA members get an Enhanced entry for free – included in your membership fee.

# AER Guidelines for 2022

The Guidelines have been reviewed and updated – a BIG thank you to Matteo Cappai from Ipsos and Georgina Butcher, Janssen for undertaking this work for EPHMRA on behalf of the membership.

# EPHMRA Adverse Event Reporting (AER) Guidelines - Revised May 2022:

**These guidelines provide the principal requirements of Pharmacovigilance (PV) reporting for individuals or organisations involved in market research (MR) activities within the healthcare industry. This includes those working for a Marketing Authorisation Holder (MAH), Market Research Organisation (MRA) or other organisations involved in MR activities. It applies to employees and contractors working with or for a MAH, MRA or other organisations engaged in MR.**

The principles relate to global PV requirements with particular reference to the European Medicines Agency's (EMA) Guideline on Good Pharmacovigilance practices (GVP), Module VI for the 'Collection, management, and submission of reports of suspected adverse reactions to medicinal products'[1].
(ref. EMA 28 July 2017EMA/873138/2011 updated August 2017, Rev 2) and also the Regulation (EU) 2017/745 on medical devices (CHAPTER VII; POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE) that became applicable on 26 May 2021 within the European Union.

## EPHMRA Members' Responsibilities

- MRAs and MAHs should comply with global, regional and local regulatory Pharmacovigilance requirements, and with consideration to global, regional and local codes and regulations, including data protection laws.
- These guidelines apply to MRAs, including subcontractors, fieldwork agencies, analysts, interviewers, and MAH functions, e.g. global/regional/local market researchers, commercial / marketing, medical, health economics & outcomes research (HEOR), Market Access and others involved in MR activities.

## 1.INTRODUCTION

### Pharmacovigilance

Pharmacovigilance (PV) is *'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem'.*[2]

Before a regulator authorises a medicine or medical device for use, evidence on the safety and efficacy is limited to clinical trials conducted in defined patient population(s) and for relatively short time periods. After regulatory authorisation the medicine or the medical device may be used in a broader patient population and for longer time periods where new or an increase in known side effects may appear.

The Marketing Authorisation Holder (MAH) is responsible for monitoring, collecting, and reporting suspected adverse events associated with medicinal products (medicines) or medical devices for human use including prescription and non-prescription, e.g. over-the-counter (OTC), and managing the safety of all its medicines and medical devices during their use in healthcare practice.

### Basis of Guidelines

EPHMRA's Adverse Event Reporting Guidelines detail the scope of the responsibilities and requirements of the process for Adverse Event reporting for market research activities.

These Guidelines outline best practice for MRAs on collecting, forwarding, and managing Adverse Events, Special Reporting Situations, and Product Complaints for medicines and medical devices (refer Definitions). It applies to market research connected with medicinal products or medical devices in therapeutic areas authorised for human use where a company has responsibilities as a Marketing Authorisation Holder (MAH) / Certificate Holder. It does not apply to:

- In-licensing opportunities or when a company is not the MAH/Certificate Holder;
- Clinical trials.

The term 'Adverse Event' is used as an umbrella term within these guidelines. It encompasses Adverse Events (AE), Special Reporting Situations (SRS), and Product Complaints (PC). Refer Definitions.

# 2.DEFINITIONS

## 2.1 Adverse Event (AE)

An Adverse Event is an unintended and unfavourable response to a medicine, whether or not considered to be related to the medicine or medical device (i.e. causal relationship).

Where it is reasonable to assume a causal relationship with a medicinal product this is referred to as an Adverse Reaction (AR). The MAH PV will assess to determine if there might be a causal relationship or not for the purpose of AE reporting. It is not the role for market research to do this and as such the term AE is used in the EPH MRA AER Guidelines.

## 2.2 Special Reporting Situations (SRS)

Situations where a medicine is used outside of the marketing authorisation, including:

- **Overdose or Lower dose**: use per administration or cumulatively above the recommended authorised maximum dose.
- **Off-label use**: intentionally used for a purpose not within the intended use or authorisation for the medicine.
- **Misuse**: intentional and inappropriate use outside of the marketing authorisation for the medicine.
- **Abuse**: persistent or sporadic, intentional excessive use of a medicine accompanied by harmful physical or psychological effects [DIR Art 1(16)].
- **Occupational exposure**: contact with a medicine as a result of professional or non-professional occupation, e.g. splitting or cutting capsules and tablets.
- **Medication error**: includes dispensing errors, accidental exposure, maladministration.
- **Lack of, or unexpected, therapeutic effect**: where an additional benefit not previously known is reported.
- **Drug or drug-food interactions**: effectiveness or toxicity of one medication is altered by the administration of another medicine(s), foods interfering with medication, e.g. grapefruit or grapefruit juice with some statins and other medicines.
- **Note:** MAH and MRA to agree additional SRSs, e.g. hospitalisation, pregnancy, breast feeding, transmission of infective agent, etc.

## 2.3 Product Complaint (PC)

Includes suspected failure of a medicine, damaged, missing, incorrect strength or colour of medicine, damaged packaging, missing patient information leaflet, broken or damaged needle or syringe, counterfeit medicine, etc.

## 2.4 A medical device[3]

Any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for specific medical purposes.

## 2.5 In vitro diagnostic medical device[4]

Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information.

# 3.RESPONSIBILITIES FOR AE REPORTING FOR MARKET RESEARCH STUDIES

## Who is responsible?

- **All MAH personnel** (e.g. market research, business intelligence/information, marketing, etc) and including representatives and contractors.
- **All Market Research Agency (MRA) personnel** working on behalf of the MAH, including the agency, sub-contractors, recruiters and fieldwork, interviewers, analysts, etc.
- MRAs should have a contract in place with all their suppliers on the required AE reporting process.

## Responsibilities and processes

- The MAH is primarily responsible for compliance with global, regional, and local PV regulations and for assessing whether MR studies may generate AEs, SRSs, or PCs.
- Where a MAH engages an MRA to provide MR services, explicit procedures and detailed agreements for AE reporting should be put in place, i.e. contractual arrangements, to ensure the MAH can comply with regulatory requirements.
- The MAH's PV is responsible for managing reporting of the Individual Case Safety Report (ICSR), recording incomplete AE reports (not a valid ICSR), and all associated follow-up actions, if appropriate.
- The MRA can only provide the contact details of the AE Reporter, whether a HCP, patient, carer or other, to the MAH if there is a lawful basis for this under the relevant data protection legislation.
- There may be different legal basis to process personal data depending on jurisdictions. Market research studies most commonly use the data subject's (refer Note below) consent as a lawful basis for the transfer of personal data, but this is not the only option.
- If consent is used as the lawful basis for the transfer of personal data, this is a separate data processing operation and requires the participant's consent, whether a HCP, patient, carer or other. This may be done at the end of the interview.
- Where the MRA subcontracts its MR obligations to a third party, e.g. a fieldwork agency, it should ensure the subcontractor undertakes AE reporting to comply with all legal, regulatory, and contractual requirements in general.
- Co-promotion or co-marketing situation: the MRA should agree with the commissioning company the process for AE reporting.

**Note: 'Data subject'** is used in the EPHMRA guidance in line with GDPR terminology rather than participant or research subject.

## Responsibilities to Data subjects

All data subjects, whether HCPs or patients, should be informed at appropriate times (e.g. at recruitment, start of interview), of the requirement for MAH's to report AEs arising during MR.

## Disclosure of Transfer of Value

- In general, disclosure requirements under European Federation of Pharmaceutical Industries and Associations (EFPIA) code, 2019[5] and the US Physicians Payment Sunshine Act, 2010[6] relating to Transfer of Value (**ToV**) do not require MRAs to identify the names of the HCPs who report AEs during MR studies.
- These are considered as solicited AE reports. The HCP's personal data are provided to the MAH's PV for the purpose of AE reporting only and is dependent on the HCP's consent to pass the information.

## 4.AE REPORTING REQUIREMENTS

- The MRA should agree the AE reporting requirements with the MAH at the start of MR but before recruitment and fieldwork start.
- The MRA should also agree AE reporting requirements with the MAH associated with **medical devices** as these may differ compared to medicinal products.
- AEs for any medicines or medical devices where the commissioning client holds the marketing authorisation need to be reported to the MAH's PV.
- AEs should be forwarded where the reporter uses either the company's brand or a generic name.
- The commissioning MAH can provide a list of the medicines and devices for which they hold the marketing authorisation for the countries included in the study, including brand and generic names, to the MRA at the start of the MR.
- MRAs are not required to collect AEs cited for other companies' medicines, or report AEs cited in groups of drugs.

Any type of AE, no matter the level of severity, should be reported by the MRA.

### 4.1 When and how to complete AERs

The AER may be completed at the end of recruitment or the MR interview – there is no need to interrupt the interview to do this.

Provide as much detail as possible to complete the information required for AE reporting (refer reporting criteria below), preferably completing it with the help of the reporter.

The MAH should provide contact details for the MRA (including sub-contractors, fieldwork) to forward AERs, i.e. email, fax number, other secure electronic method for the transfer of data. Note: Country level privacy rules for transfer of personal information should apply.

### 4.2 Quality Management and Training

The MAH and MRAs should have clear and comprehensive operating procedures in place for the collection, forwarding and management of Adverse Events.

PV training requirements including AER should be agreed between the MAH and MRA before the start of the MR (some differences between MAH's requirements).

PV training including AER must be undertaken to ensure all individuals directly involved understand the requirements and what actions is needed.

The MAH should supply their AER form, or the EPHMRA AER template may be used (access to the electronic system can be arranged).

### 4.3 Categories of AE sources for Market Research studies

There are two types of AE reports in the post-authorisation phase: "*reports originating from unsolicited sources and those reported as solicited.*"[7]

Usually AEs reported during MR studies are solicited, but it's important to recognise those that arise as unsolicited, spontaneous AEs.

- **Solicited**: includes AEs "*derived from organised data collection systems, including surveys of patients or healthcare professionals*"[8], e.g. personal/telephone/web-based interviews, surveys (paper, online, etc).
- **Unsolicited**: *"not related to any organised data collection systems"*[9] e.g. syndicated studies, social media/ digital listening (EMA classify as internet/digital media as unsolicited spontaneous).

Solicited and unsolicited AEs during MR studies with healthcare professional and / or consumers (refer definitions below) should be reported to the MAH's PV.

### 4.4 Primary sources of AEs: Healthcare Professionals and Consumers

**Healthcare Professional (HCP):** *"defined as a medically qualified person, such as a physician, dentist, pharmacist, nurse, coroner or as otherwise specified by local regulations"*[10]

**Consumer:** *"is defined as a person who is not a healthcare professional such as a patient, lawyer, friend, relative of a patient or carer".*

**NOTE:** EPHMRA guidelines use **patient** as the more familiar and most used term in the healthcare industry, rather than consumer. However, it is important to note AE reporting still applies other types of 'non-HCP' participating in MR studies, e.g. a relative, friend or carer of the patient.

### 4.5 AE Reporting criteria

The MAH's PV is responsible for managing and reporting valid Individual Case Safety Reports (ICSR) of suspected AERs to the relevant regulatory authorities. Four minimum criteria are required for a valid ICSR (see below).

The MAH's PV is expected to follow-up AERs where information is missing.

### 4.6 Minimum criteria for valid ICSRs

a. One or more identifiable reporter(s),
b. Identifiable patient or group of patients,
c. One or more suspected medicinal product(s) or medical device(s),
d. Suspected Adverse Event.

- **Reporter:** characterised by their qualification, e.g. physician, pharmacist, or patient, name or initials, address (e.g. organisation, department, street, city, zip or postcode, country), email or telephone/cell/mobile number.
- **Patient:** characterised by at least one of the following qualifying parameters: initials, data of birth, age/age group, or gender/sex.
- **Medicinal product or medical device**: medicine(s) or medical device(s) where the commissioning client is the MAH (identified by brand or generic name).
- **Suspected Adverse Event**: includes serious and non-serious AERs, SRSs and PCs.

## 5.CONSENT AND AE REPORTING

### 5.1 Transfer of personal information in AERs

- The reporter's personal information, e.g. name, contact details, can only be forwarded to the MAH if the participant has provided consent or there is an alternative lawful basis in place[11] (refer GDPR, 2018).
- If consent is being used this must be provided before any data are transferred by the MRA to the MAH.
- Personal information must not be forwarded to the MAH if consent has not been given, or there isn't another alternative lawful basis in place (e.g.: Legitimate Interests supported by a Legitimate Interest Assessment; note: the lawful basis has to be agreed before any processing can take place) although the subject can still take part in the MR. Under these circumstances the MRA must forward AEs as an anonymous report.
- If the reporter has already notified the relevant authorities or MAH, AEs from MR should still be forwarded to the MAH.
- When relying on consent for receiving and transferring personal data the sponsoring organisation could be named when personal information is obtained during MR (GDPR, 2018). For very specific studies, such as in-licensing or requirement of local codes, e.g. Denmark, the sponsor should not be identified.
  The respondent should provide their consent to participate on this basis (preferably documented) or decline.

- Consent for processing personal data for AE reporting purposes may be obtained at the start or end of the interview, as it is not essential for participating in MR.
- Information about an AE from a MR subject that relates to someone else's experience e.g. a patient's carer, relative or friend, it must be reported to the MAH without the personal details of the individual who experienced it as they have not consented to their details being forwarded[12].

### 5.2 Patient 'special category' personal data

- Personal data that is especially sensitive is classed as 'special category' and requires additional security.
- 'Special category' personal data (GDPR, 2018) includes race or ethnicity, sexual orientation, biometric or genetic data, religious beliefs, data on health problems.
- Patients must provide explicit consent if they are providing 'special category' personal data.

The above refers to EU GDPR, 2018 regulation for guidance. The MRA should check applicable local and regional data protection requirements and agree with the MAH how this should be managed at the start of the MR. This should apply to the full data management process and documented (e.g. contract).

## 6.REPORTING AEs

- AEs must be reported to the MAH within one business day of the MRA or their subcontractor becoming aware of it.
- The only exceptions are:
  - Syndicated studies (either based on primary or secondary MR) where data are collected independently of individual companies and are available for purchase by multiple Healthcare companies.
  - Longitudinal patient databases.

## 7.REPORTING FORMATS

The two common AE reporting formats are:

- **AER Form**: collecting information during a MR interview, e.g. personal or group interviews. There is no need to interrupt the flow of the interview as the form can be completed at the end. Collect as many details as possible for minimum reporting criteria. The MRA employee/interviewer/agency fieldworker collecting the information or the person filling in the reporting form is responsible to sign the AE reporting forms before these are forwarded to the MAH. **Tabulation of aggregate data**: information provided in tables for review in aggregate or a large volume of AEs is anticipated, e.g. online surveys, particularly those collecting data on prescribing behaviour and potentially conjoint studies. The reporting format typically includes the number of MR subjects citing AEs but should be agreed with the MAH before the MR starts.

**Refer EPHMRA AE Reporting Form template**

### 7.1 Format of AE Tabulations

AER tabulations, e.g. structured or semi-structured surveys, should include:

- Number of MR subjects where an AE was cited;
- Question base i.e. how many MR subjects answered the question.

The **format** should be agreed with the MAH in **advance of data processing.**

## 7.2 AE Reconciliation Process

Confirmation and/or reconciliation of AEs is a requirement upon completion of a MR study.

A summary of all AEs identified during the MR is to be 'reconciled' with or checked against the individual AEs forwarded to the MAH's PV during the MR to ensure all AEs are accounted for. The MRA should agree the reconciliation process as some MAHs use a digital AER system.

The reconciliation form should be completed at the time period agreed at the start of the study or contract with the MAH's PV (e.g. end of fieldwork or study), even if no AEs were reported, i.e. report as "0" or "No AEs".

This applies to irrespective of whether information is collected using AE Report Form or tabulation of aggregate data.

The AER Reconciliation form should include for each country where MR was undertaken, the number of AEs identified (not just reported), summary by each AE of MR subject's ID, the medicine or medical device, and the AE details.

## 7.3 Syndicated Studies

There is no legal responsibility for the MRA to forward AEs for syndicated studies. Syndicated primary market research studies are conducted by the MRA independently of any healthcare company (e.g. pharmaceutical, Biotech) and the results and data purchased by multiple clients.

Responsibility to collect AEs lies with the MAH that purchases the syndicated data.

The MAH should forward an AE identified from a purchased syndicated study to their PV. The MAH may however request the MRA to provide the data in an appropriate AER format.

Where confidential or proprietary questions are added to a syndicated survey by a MAH, the data from these questions must be treated in the same way as MR commissioned by the MAH, i.e. the MRA should forward AEs to the MAH's PV.

## 7.4 Longitudinal Patient Databases

Longitudinal patient databases e.g. GPRD (General Practice Research Database) are out of scope.

The Council for International Organisation of Medicinal Sciences (CIOMS ) suggests that there is no obligation to search through such databases for individual AEs as this will give rise to spurious signals and conclusions however if they are found (deliberately or co-incidentally), they should be forwarded to the MAH.

Data from longitudinal patient databases are different to tabular AE summaries collected from MR as they have not arisen from a defined project and are for multiple users, not just acquired by an MAH for internal use (unlike commissioned MR).

## 7.5 AE reporting where social media is used in MR

- AE reporting requirements apply where social media, or social media associated techniques (e.g. online communities) are used as a source of MR data, i.e. treated as any other type MR study. The MAH and MRA should agree the process for collecting and reporting AEs associated with their medicinal products or medical devices before the start of the study.
- This applies to public and private sites, passive, and active approaches and to company sponsored and non-company sponsored websites, which should be monitored during fieldwork for AEs.
- If a company chooses to listen-in to or 'scrape' from non-company sponsored sites, whether public or private (with consent) it is recommended that the 'listened' to pages should be monitored for AEs for the period of the listening-in activity only.

- There is no obligation for researchers to monitor non-company sponsored sites routinely for AEs if they are not being used for a MR purpose.

### 7.6 Who to Direct Queries To?

MRAs should direct queries relating to the AER process to the MAH's PV or MR contact as this is the most important source for guidance.

## RESOURCES - WEBSITES:

- EPHMRA website
- BHBIA website (UK)
- CMS's final rule on the Sunshine Act: www.federalregister.gov/ articles/2013/02/08/2013-02572/medicare-medicaid-childrens- health-insurance-programs-transparency-reports-and-reporting-of
- European Union website
- European Medicines Agency
- https://www.cms.gov/OpenPayments/Downloads/Affordable-Care-Act-Section-6002-Final-Rule.pdf
- Physician Payment Sunshine Act Final Rule: Definitions, Policy and Medicine, Feb. 5, 2013: www.policymed.com/2013/02/physician- payment-sunshine-act-final-rule-definitions.html
- US Government Sunshine Act

## Glossary of abbreviations

| | |
|---|---|
| AE | Adverse Event |
| AER | Adverse Event Reporting |
| AR | Adverse Reaction |
| EMA | European Medicines Agency |
| EU | European Union |
| HCP | Healthcare Professional |
| ICSR | Individual Case Safety Report |
| MAH | Marketing Authorisation Holder |
| MR | Market Research |
| MRA | Market Research Agencies (including company and/or individuals conducting MR, including subcontractors, fieldwork analysts and interviewers) |
| PC | Product Complaint |
| PSUR | Periodic Safety Update Report |
| PV | Pharmacovigilance |
| SRS | Special Reporting Situations |

Footnotes:

1 https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-submission-reports_en.pdf (accessed 05/02/2020)

2 The European Medicines Agency website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000258.jsp&mid=WC0b01ac0580b18c76 (accessed 05/02/2020)

3 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

4 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

5 https://www.efpia.eu/media/413022/efpia-code-2019.pdf Transfers of Value (ToV), p8 (Direct, or indirect where the Member Company knows or can identify the Recipient who will benefit from the ToV

6 https://www.govinfo.gov/content/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf (accessed 23/02/2020), SEC. 6002. PUBLIC LAW 111–148—MAR. 23, 2010 TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

7 EMA GVP, Module VI (Rev 2), EMA/87138/2011, Section VI.B.1. Collection of individual safety reports

8 EMA GVP, Module VI (Rev 2), EMA/87138/2011, Section VI.B.1.2. Solicited reports

9 EMA GVP, Module VI (Rev 2), EMA/87138/2011, Section VI.B.1.1.1. Unsolicited spontaneous reports

10 EMA GVP, Module VI (Rev 2), EMA/87138/2011, Section VI.A.1.4. Primary source, healthcare professional, consumer

11 European Union (EU) Regulation (EU) 2016/679, (April 2016). General Data Protection Regulation. Came into force May 2018. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1532348683434&uri=CELEX-:02016R0679-20160504 (accessed 26/02/2020).

12 https://www.bhbia.org.uk/guidelines-and-legislation/AE-PC-SRS-Guidance (accessed 21/02/2020). BHBIA/ABPI (2018). Guidance notes on collecting adverse events, product complaints and special reporting situations during market research. August 2018, Section 4.2, p7

research partnership

# The rise, acceleration and acceptance of telehealth adoption

**Marietta Fernandes** Associate Director

**'Healing at a distance' is the literal meaning of telemedicine. According to the World Health Organisation, it is defined as the use of ICT to improve patient outcomes by increasing access to care and medical information, incorporating new advancements in technology and responding and adapting to the changing health needs and contexts of societies.**

Within this context, it goes without saying that Covid-19 has led to a big push towards digital healthcare solutions. Until 2020, the adoption of telemedicine across Europe was fairly slow and limited, but social distancing requirements and the consequent advancements in technology facilitated its accelerated adoption in healthcare systems.

Indeed, a Digital Health Trends survey conducted by Research Partnership and Sermo back in **March 2021** (with a mix of HCPs in the US, EU5 and China) reported that nearly 70% of HCPs regularly used telemedicine – as well as other digital healthcare solutions, – during the pandemic.

Furthermore, another qualitative study we carried out with patients and HCPs in the US, Germany and China in **May/June 2021** reported positive experiences with telemedicine on both sides for convenient, time-saving consultations. HCPs also felt it was helpful to have more time to reassure and empathise with patients, with less time-pressure and more relaxed consultations.

*"We have learned new ways of working during Covid. Some are now the best ways of delivering care."*
**Ophthalmologist, UK (Nov, 2021)**

### The scales seemed to be tipping back towards face-to-face

But how did the utilisation of telemedicine fluctuate as the pandemic evolved? A third survey we conducted in **November 2021** (with n=157 HCPs in both primary and secondary care in the EU4 and UK) revealed that physicians were increasing their volume of face-to-face interactions with patients and felt mostly positive about this. Attitudes varied by region, however, with UK physicians spending only 60% of their time in direct face-to-face consultations, versus ~80% in France and Italy. UK GPs in particular, were spending close to 40% of their time in teleconsultations in contrast to lower averages (~25%) in other markets.

The reluctance of UK GPs to return to face-to-face consultations may have been the reason for the government's move to provide incentives. In October 2021, it was announced that GPs in England would receive £250m to improve their services, but only if they increased the number of patients being seen face-to-face under a new government and NHS action plan. This drive had been cited as a way to relieve growing pressures on A&Es, which the government attributed to patients not having access to see GPs in person (although disputed by the Royal College of GPs in September 2021).

Only 58% of patients were seen face-to-face in August 2021 (the first full month following the ending of restrictions), compared with 54% in January 2021 and more than 80% before the pandemic, which correlated with our survey. A behavioural shift back to face-to-face interactions correspondended with the results from our survey highlighting mixed perceptions on satisfaction with telehealth.

Those physicians reporting lower to moderate satisfaction began to see an opportunity to return to face-to-face consultations and overcome some of the perceived underlying telehealth challenges pertaining to managing patient compliance (37%), remote diagnostics (35%) and overall disease management (32%).

The perceived preference for face-to-face consultations was also reflected in our previous research that highlighted lingering doubts about telemedicine, most notably the reliability of remote diagnostics for more complex cases, especially if HCPs were dependent on patients correctly and confidently, carrying out self-assessments.

This theme tied in with patient apprehension over aspects such as accurate diagnosis and patient desire for in-person consultations to build rapport with their physicians. Limited online prescription services and data privacy were also cited as concerns from both the HCP and patient perspectives.

### Finding the right balance with a hybrid approach

Bearing in mind these challenges, is this an indication that we are seeing a return to the face-to-face model? Not entirely. HCPs were already seeing some success with video consultations and this is expected to continue. More than half the doctors in our study expected to use video consultations to manage patients in the next 3 years, with 20% expecting to use it a majority of the time. GPs, especially in the UK, did not expect to return to solely in-person consultations in contrast to other specialities who anticipated more face-to-face interactions. Another key point from our research was that a hybrid model would be strongly based on using the most appropriate consultation type dependent on the circumstance, with many in favour of using teleconsultations for routine follow-up appointments.

*"Really, I still need face-to-face and in-person interaction for some phases of the clinical process."*
**Dermatologist, Spain (Nov, 2021)**

*"I hope to return to face-to-face limiting telehealth to scheduled 'follow-up' appointments, in absence of disease variation."*
**Cardiologist, Italy (Nov, 2021)**

This finding was corroborated by other studies conducted at Research Partnership that showed user experience with telemedicine had mainly been positive. Moreover, there was consensus that usage would become established in the future alongside in-person appointments, dependent on the stage of the patient's journey. In the UK, for example, this scenario is included in the NHS Long Term Plan to optimise and increase the range of digital health tools and services.

*"People will be able to seek health information and support online and choose whether they speak to a doctor on the phone or in person. A wide range of NHS-approved apps will help people get ongoing support to help them manage their health and wellbeing needs, backed up by face-to-face care when this is needed."*
**Physician, UK (Nov 2021)**

### Future digital transformation

Considering what we have learned since the start of the pandemic, it is valid to conclude that technological advances are swift – as seen with some markets trialling telemedicine apps/platforms – and digital health tools will continue to develop and improve at speed. In this sense, there are expectations that current telemedicine gaps will be filled. Consequently, the hybrid model may extend beyond routine follow-ups and will be utilised confidently for clinical purposes such as diagnosis, resulting in convenience and time benefits, as well as potential health economic cost savings in the long run.

**To find out more, please contact:**
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# Activating Insights with Systemic Design: Implement Lasting Measures in Healthcare Systems

Jelena Bebić, Senior Research Consultant Healthcare,
Point Blank Research & Consultancy GmbH

Research X Design – our motto at Point Blank – describes an invaluable symbiosis for activating insights. This is especially true for the healthcare sector, which is characterized by its complexity. In order to create impact in this context, you need systemic thinking: this means embedding insights and possible solutions in existing products and processes in the healthcare ecosystem and creating interfaces between them. With the help of Systemic Design, we can develop compatible solutions that have lasting effects on the optimization of the entire system.

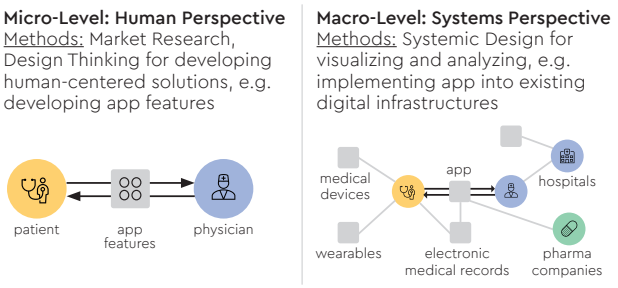



*Figure: Micro- and macro-level in comparison as used in app development*

**The Idea:**
**Grounding & Activating Insights Through Systemic Design**
All too often, insights from market research are not consistently implemented. One reason for this is the fact that they are not properly transferred from the study participant's individual perspective into the "big picture" of the healthcare sector. Existing products, processes and services of different stakeholders often are not fully taken into account, making implementation difficult.

A change in perspective can help: first, market research results, e.g. from interviews with patients, are verbalized as insights which then help to create solutions that are centered on the *patient's needs*. Bridging the gap between the individual's perspective and the big picture is helpful in developing *lasting* solutions.
Systemic Design fills this gap by visualizing relevant structures and processes connected to the stakeholders concerned. Based on Systems Thinking, we can define and analyze components of a system – e.g. stakeholders, products, services – and the relationships between them. It complements the human-centered approach of Qualitative Market Research and Design Thinking with a higher-level perspective and contextualizes the insights. This synergy ensures an integrated approach, especially for interventions in complex problems in healthcare (De Savigny & Adam, 2009; Mugadza, 2015).

**The Procedure:**
**1. Provide an Initial Overview**
- Outline stakeholders and existing structures as a basis for initial hypotheses: Which stakeholders are key to the success of the project? Which services already exist? Which problems are already known?

**2. Research, Analyze and Formulate Insights**
- Adapt interview questions based on the initial overview
- Analyze research results with the help of the overview
- Formulate insights while taking into account the individual participant's perspective and the system as a whole. What are the pain-points on the patient side? Are there systemic causes for these, are there effects on a product or process?

**3. Visualize the Ecosystem and Apply the Insights**
- Outline the relationships, processes, and information flows between the stakeholders. Which processes take too long? How can we mitigate this? Where are gaps in the system that we need to bridge?
- Apply ideas (e.g. from workshops with study participants): What changes in the system if we insert idea A in place X? What are the resulting recommendations?

**4. Activate Insights by Utilizing the System**
- Use the system as a strategic playground in internal workshops: What does this entail in terms of strategy at the micro level, what at the macro level? What are the next steps and measures?
- For future-proof measures, also consider trends and your own strategy: How will the situation or the system have changed in five years?
- Use Design Thinking methods to develop ideas at the micro-level: How do we create human-centered solutions to existing and future challenges?

**Key Takeaways:**
**01 Research x Systemic Design = Lasting Solutions in the System!** Visualizing with a Systemic Design approach helps to correctly assess individual opinions and ideas and to derive viable recommendations for the project.

**02 Don't be Afraid of Complexity!** Initially, an increase in complexity is inevitable to provide decisive recommendations. This way, interrelationships become clear, and the consequences of system-changing ideas can be assessed.

**03 Flexible Change of Perspective as a Strategic Tool!** Transform your body of knowledge into a strategic tool that can be zoomed into or out of as needed:
- Macro-level = patterns and long-term changes, Systemic Design supports analyzing and strategic planning
- Micro-level = human need, Design Thinking supports prototyping of tangible interventions (IDEO U, 2022).

For further information on Systemic Design in Market Research, please contact jelena.bebic@point-blank.net.

Sources

De Savigny, D. & Adam, T. (2009). *Systems thinking for health systems strengthening.* Alliance for Health Policy and Systems Research, WHO. DOI:10.13140/RG.2.1.4720.4325.

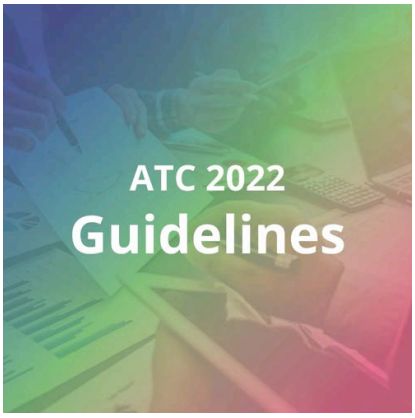
IDEO U. (2022). *How to Think in Systems for Greater Impact.* https://www.ideou.com/blogs/inspiration/how-to-think-in-systems-for-greater-impact.

Mugadza, G. (2015). Systems Thinking and Design Thinking: Complimentary Approaches?. *Systems Thinking World Journal: Reflection in Action.* [Online Journal]. 3. [Referred 2015-2-9]. ISSN-L 2242-8577.

# Committee Updates

## ATC Classification

https://www.ephmra.org/classification/anatomical-classification/




The Anatomical Classification of Pharmaceutical Products has been developed and maintained by the European Pharmaceutical Marketing Research Association (EPHMRA) and is therefore the intellectual property of this Association. EPHMRA's Classification Committee prepares the guidelines for this classification system and takes care for new entries, changes and improvements in consultation with the product's manufacturer.

The contents of the Anatomical Classification of Pharmaceutical Products remain the copyright to EPHMRA. Permission for use need not be sought and no fee is required. We would appreciate, however, the acknowledgement of EPHMRA Copyright in publications etc.

Users of this classification system should keep in mind that Pharmaceutical markets can be segmented according to numerous criteria.

### 2022 ATC Vote

Industry members have been emailed the 2022 ATC vote.

## Classification Development Proposals for Vote in 2022; implementation in 2023.

### Proposal 1

**Platelet-enhancing products**

The proposal is to create a new grouping of platelet-enhancing products to include thrombopoietin agonists (current class B2E) and other substances such as thrombopoietin growth factors. The enhanced class B2E will have two subclasses, one for the thrombopoietin agonists and the second for other platelet-enhancing products.

Currently, products such as fostamatinib and oprelvekin are classified in B6X (Other haematological agents) with other unrelated products, so this new proposal will bring together related products.

B2E PLATELET-ENHANCING PRODUCTS

B2E1 Thrombopoietin agonists
Includes products containing thrombopoietin agonists for thrombocytopenia, eg avatrombopag, eltrombopag, lusutrombopag, romiplostim, etc.

B2E9 Platelet-enhancing products, other
Includes products for thrombocytopenia containing fostamatinib, oprelvekin, etc.

### Proposal 2

**HIV antivirals – multiclass combinations**

The proposal is to create a new fourth level class for products containing combinations of different types of HIV antiviral. These combinations are currently classified in J5C9 (HIV antivirals, other) together with single-substance products. This change will therefore provide a clear separation of these combinations.

J5C8 HIV antivirals, multiclass combination products

Includes products containing two or more substances from different HIV subclasses. For example, an integrase inhibitor in combination with a nucleoside reverse transcriptase inhibitor.

Combinations of HIV antivirals from a single class are classified in that relevant specific class, eg a product containing only nucleoside reverse transcriptase inhibitors is classified in J5C1.

## Introduction of NFC Classification


The THREE LETTER CODE (TLC) was introduced as a dosage Form Code in the audits during the middle of the 1960s.

A large number of new dosage forms have appeared since that time and it was considered that revision of the system was required in order that a unified, worldwide classification could be developed. The Annual General Meeting of EphMRA in 1984 decided to create a Working Party to discuss suggested improvements to the classification, and members were appointed from representative countries and IMS. This group based their work upon proposals which were already under consideration between some members and IMS.

The result of the Working Party deliberations was the NEW FORM CODE (NFC) which was accepted for worldwide introduction at the 1985 AGM of EphMRA. At that meeting it was also agreed that the New Form Code Committee should assume responsibility for further improvements and development of the NFC in addition to the allocation of correct codes.

You can also find on the web site the 2022 NFC files: https://www.ephmra.org/classification/new-form-codes/

## NFC Guidelines 2022

NFC Guidelines

NFC Summary of Changes

NFC Summary of Class Changes

NFC Poster

### JANUARY 2022

IQVIA

**NFC**
New Form Code

**FIRST LETTER**

A.. Oral Solid Ordinary
B.. Oral Solid Retard or Long-acting
D.. Oral Liquid Ordinary
E.. Oral Liquid Retard or Long-acting
F.. Parenteral Ordinary
G.. Parenteral Retard or Long-acting
H.. Rectal Systemic
I.. Nasal Systemic
J.. All other Systemic
K.. Oral Topical
M.. Topical, Dermatological, Haemorrhoidal, External
N.. Ophthalmic
P.. Otic
Q.. Nasal Topical
R.. Lung Administration
T.. Vaginal/Intra-Uterine
V.. Non-Human Use and Others e.g. Laboratory Tests, etc.
Z.. Unknown

**MIDAS AND NATIONAL DATABASES**

| | |
|---|---|
| NFC1 = A | All oral solid ordinary forms |
| NFC12 = AC | All ordinary capsules |
| NFC123 = ACD | All ordinary enteric-coated capsules |
| NFC2 = M | All ampoules |
| NFC23 = MB | All dry ampoules |

| VERTICAL SECOND LETTER | HORIZONTAL THIRD LETTER | ..A | ..B | ..C | ..D | ..E | ..F | ..G | ..H | ..J | ..K | ..L | ..M | ..N | ..P | ..Q | ..R | ..S | ..T | ..V | ..W | ..X | ..Y | ..Z |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| .A. | Tablets | Tablets .AA | Orally Disintegrating Tablets .AB | .AC | .AD | Buccal Tablets .AE | Sublingual Tablets .AF | Chewable Tablets .AG | Effervescent Tablets .AH | Layered Tablets .AJ | Soluble Tablets .AK | .AL | .AM | .AN | .AP | .AQ | .AR | .AS | .AT | .AV | .AW | Enema Tablets .AX | Other Tablets .AY | Combi-Pack Tablets .AZ |
| .B. | Coated Tablets | Coated/ Sugar-Coated Tablets .BA | Gelatin-Coated Tablets .BB | Film-Coated Tablets .BC | Enteric-Coated Tablets .BD | .BE | Sublingual Coated Tablets .BF | Chewable Coated Tablets .BG | .BH | .BJ | .BK | .BL | .BM | Membrane-Coated Tablets .BN | .BP | .BQ | .BR | .BS | .BT | .BV | .BW | .BX | Other Coated Tablets .BY | Combi-Pack Coated Tablets .BZ |
| .C. | Capsules | Capsules .CA | .CB | .CC | Enteric-Coated Capsules .CD | Buccal Capsules .CE | Biting Capsules .CF | Chewable Capsules .CG | .CH | .CJ | .CK | .CL | .CM | Membrane Capsules .CN | .CP | .CQ | .CR | Cachets .CS | Inhaler Capsules .CT | Capsules Topical Application .CV | .CW | .CX | Other Capsules .CY | Combi-Pack Capsules .CZ |
| .D. | Solid Special Forms | .DA | .DB | .DC | Pellets .DD | Lozenges .DE | Chewing Gum .DF | Sweets/ Candy/ Bonbons .DG | .DH | .DJ | .DK | .DL | .DM | Ocular/ Therapeutic Systems .DN | .DP | Cubes .DQ | Cakes/ Chocolates/ Bars/ Biscuits .DR | Globules .DS | .DT | .DV | .DW | .DX | Other Special Solids .DY | Combi-Pack Special Solids .DZ |
| .E. | Powders/ Granules | Powders .EA | Granules .EB | Dusting Powders/ Dermatological .EC | Medicinal/ Pharmaceutical Powdered Substances .ED | .EE | Sublingual Powders/ Granules .EF | .EG | Effervescent Powders/ Granules .EH | .EJ | Soluble Powders/ Granules .EK | .EL | Unit Dose Pwd Inhal Non-Refillable .EM | Unit Dose Pwd Inhal Refillable .EN | Unit Dose Powders/ Granules .EP | .EQ | .ER | .ES | .ET | .EV | .EW | Enema Powders .EX | Other Powders/ Granules .EY | Combi-Pack Powders/ Granules .EZ |
| .F. | Gases | Gases for Inhalation .FA | .FB | .FC | .FD | .FE | .FF | .FG | .FH | .FJ | .FK | .FL | .FM | .FN | .FP | .FQ | .FR | .FS | .FT | .FV | .FW | .FX | .FY | .FZ |
| .G. | Liquids | Liquids .GA | Liquid Drops .GB | Sprays without Pressure .GC | Collodion/ Lacquers .GD | Liquids for Inhalation .GE | Sublingual Liquids/ Drops .GF | .GG | Oils .GH | Dry Suspensions/ Syrups/Drops .GJ | Liquid Suspensions .GK | Liquid Emulsions .GL | Syrups .GM | Unit Dose Liquids .GN | Metered Dose Liquids .GP | Preservative-Free Multi-Dose Liquids .GQ | Spirits/ Wines .GR | Lotions .GS | Shaking Mixture/ Dermatological .GT | .GV | Liquid Soaps/ Washes .GW | Enema Liquids .GX | Other Liquids .GY | Combi-Pack Liquids .GZ |
| .H. | Pressurised Aerosols | Pressurised Aerosols .HA | .HB | Pressurised Powders .HC | .HD | .HE | .HF | .HG | .HH | .HJ | .HK | .HL | Breath-Actuated MDI .HM | Breath-Actuated CFC-Free MDI .HN | Metered Dose Aerosols .HP | CFC-Free Metered-Dose Inhaler .HQ | .HR | Pressurised Ointments and Creams .HS | Pressurised Foams .HT | .HV | Pressurised Soaps/ Washes .HW | .HX | Other Pressurised Aerosols .HY | Combi-Pack Pressurised Aerosols .HZ |
| .J. | Baths | Baths .JA | Solid Substances for Baths .JB | .JC | .JD | .JE | .JF | .JG | Bath Oils .JH | .JJ | .JK | Bath Emulsions .JL | .JM | .JN | Partial Baths .JP | .JQ | .JR | Foot Baths .JS | Foam Baths .JT | Bath Tablets .JV | .JW | .JX | Other Baths .JY | Combi-Pack Baths .JZ |
| .K. | Teas | Teas .KA | Tea Extract Liquids .KB | .KC | .KD | .KE | .KF | .KG | .KH | Instant Teas .KJ | .KK | .KL | .KM | .KN | .KP | Tea Bags .KQ | .KR | .KS | .KT | Tea Tablets .KV | .KW | .KX | Other Teas .KY | Combi-Pack Teas .KZ |
| .L. | Suppositories | Suppositories .LA | Suppositories Adult .LB | Suppositories Paediatric/ Children .LC | .LD | .LE | .LF | .LG | .LH | .LJ | .LK | .LL | .LM | .LN | .LP | .LQ | .LR | Vaginal Suppositories .LS | .LT | .LV | .LW | .LX | Micro Enemas .LY | Other Suppositories .LZ | Combi-Pack Suppositories .LZ |
| .M. | Ampoules | Ampoules .MA | Dry Ampoules .MB | I.V. Ampoules .MC | I.M. Ampoules .MD | S.C. Ampoules .ME | Intradermal Ampoules .MF | .MG | .MH | .MJ | .MK | .ML | .MM | .MN | .MP | .MQ | .MR | Instillation Ampoules .MS | .MT | .MV | .MW | .MX | .MY | Other Ampoules .MZ | Combi-Pack Ampoules .MZ |
| .N. | Pre-filled Syringes | Pre-filled Syringes .NA | Dry Pre-filled Syringes .NB | I.V. Pre-filled Syringes .NC | I.M. Pre-filled Syringes .ND | S.C. Pre-filled Syringes .NE | Intradermal Pre-Filled Syringes .NF | .NG | Pre-filled Autoinjectors .NH | .NJ | .NK | .NL | .NM | .NN | .NP | .NQ | .NR | Instillation Pre-filled Syringes .NS | .NT | .NV | .NW | .NX | .NY | Other Pre-filled Syringes .NZ | Combi-Pack Pre-filled Syringes .NZ |
| .P. | Vials | Vials .PA | Dry Vials .PB | I.V. Vials .PC | I.M. Vials .PD | S.C. Vials .PE | Intradermal Vials .PF | .PG | .PH | .PJ | .PK | .PL | .PM | .PN | .PP | .PQ | .PR | Instillation Vials .PS | .PT | .PV | .PW | .PX | .PY | Other Vials .PZ | Combi-Pack Vials .PZ |
| .Q. | Infusions | Infusion Ampoules .QA | Infusion Dry Ampoules .QB | Infusion Vials/Bottles .QC | Infusion Dry Vials/ Bottles .QD | Infusion Bags .QE | Infusion Cartridges .QF | .QG | .QH | .QJ | .QK | .QL | .QM | .QN | .QP | .QQ | .QR | Dialysis/ Irrigation/ Perfusion Solutions .QS | .QT | .QV | .QW | .QX | .QY | Other Infusions .QZ | .QZ |
| .R. | Cartridges/Pens | Cartridges .RA | Dry Cartridges .RB | .RC | .RD | .RE | Pre-Filled Pens .RF | Dry Pre-Filled Pens .RG | .RH | .RJ | .RK | .RL | .RM | .RN | Unit Dose Cartridges .RP | .RQ | .RR | .RS | .RT | .RV | .RW | .RX | .RY | .RZ | .RZ |
| .S. | Ointments | Ointments .SA | Pastes .SB | .SC | .SD | .SE | .SF | .SG | .SH | .SJ | .SK | Emulsion Ointments .SL | .SM | Unit Dose Ointments .SN | .SP | .SQ | .SR | .SS | .ST | .SV | .SW | Soap Pastels .SX | .SY | Other Ointments .SZ | Combi-Pack Ointments .SZ |
| .T. | Creams | Creams .TA | .TB | .TC | .TD | .TE | .TF | .TG | .TH | .TJ | .TK | Emulsion Creams .TL | .TM | Unit Dose Creams .TN | Metered-Dose Creams .TP | .TQ | .TR | .TS | .TT | .TV | Cream Soaps/ Washes .TW | .TX | .TY | Other Creams .TZ | Combi-Pack Creams .TZ |
| .V. | Gels and Sols | Gels and Sols .VA | Gel Drops .VB | .VC | .VD | .VE | .VF | .VG | .VH | .VJ | .VK | Emulsion Gels .VL | .VM | Unit Dose Gels/Sols .VN | Metered-Dose Gels/Sols .VP | .VQ | .VR | .VS | .VT | .VV | Wash/ Shower Gels .VW | .VX | .VY | Other Gels/Sols .VZ | Combi-Pack Gels/Sols .VZ |
| .W. | Medicated Dressings | Plaster with Substance .WA | Cotton with Substance .WB | Gauze/ Fleece with Substance .WC | Pads with Substance .WD | Tampons with Substance .WE | .WF | Bandages with Substance .WG | Sponges with Substance .WH | .WJ | .WK | .WL | Transdermal Systems .WM | Transdermal Patches .WN | .WP | .WQ | .WR | Poultices .WS | .WT | .WV | .WW | .WX | Other Medicated Dressings .WY | Combi-Pack Medicated Dressings .WZ |
| .X. | Not in Use | .XA | .XB | .XC | .XD | .XE | .XF | .XG | .XH | .XJ | .XK | .XL | .XM | .XN | .XP | .XQ | .XR | .XS | .XT | .XV | .XW | .XX | .XY | .XZ | .XZ |
| .Y. | Other Special Forms | .YA | .YB | .YC | .YD | .YE | .YF | Food Ready to Eat .YG | Food not Ready to Eat .YH | Cigarettes .YJ | Styli and Wound Cones .YK | .YL | Sticks and Roll-Ons .YM | .YN | Bone Cements with Substance .YP | Mechanical Pessaries with Substance .YQ | Intra-Uterine Device .YR | Fumigation Candles .YS | Foams N.O.S .YT | Implants .YV | Solid Soaps/Bars .YW | Promotional Packs .YX | Other Special Forms .YY | Combi-Pack Other Special Forms .YZ |
| .Z. | Medical Aids | Plaster without Substance .ZA | Cotton without Substance .ZB | Gauze/ Fleece without Substance .ZC | Pads without Substance .ZD | Tampons without Substance .ZE | .ZF | Bandages without Substance .ZG | Sponges without Substance .ZH | Tissue Absorbable Medical Aids .ZJ | Gel and Colloid Dressings .ZK | .ZL | .ZM | .ZN | Bone Cements without Substance .ZP | Mechanical Pessaries without Substance .ZQ | .ZR | .ZS | Diagnostic Sticks .ZT | Diagnostic Tests excl. Sticks .ZV | .ZW | .ZX | .ZY | Other Medical Aids .ZZ | Combi-Pack Medical Aids .ZZ |



For a full list of the valid NFC combinations, please refer to the latest copy of the EphMRA NFC Guidelines available at www.ephmra.org

EphMRA

KeyQuest Health are delighted to announce that Bethan Williams has been promoted to Senior Project Manager. Bethan has made huge progress, both in client and project management. Clients and suppliers love working with her, and she meets day-to-day challenges with a great deal of patience and good humour! Congratulations Bethan!

In May, APLUSA obtained ISO 20252:2019 certification for "market and opinion research, data analysis, strategic and operational consulting for global healthcare markets, in compliance with applicable regulations, in order to improve the reliability of our clients' decisions and to contribute to better patient care".

Research Partnership recently joined Ashfield's consulting division, Ashfield Advisory. Commenting on the acquisition, Mary Assimakopoulos said: "This brings great opportunities to our clients, enabling us to offer the same exceptional service with the added value of being connected to the wider advisory ecosystem as and when additional support is required."