



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# EMA Patients and Consumers' Annual Training Overview: 2007-2016

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An agency of the European Union



# Analysis performed

Annual training day began in 2007

- Content description and evolution
- Participants per year
- Participants per organisation
- Outcome of training
- Continued training
- Questions for discussion





## Content of annual training day (2007-2011)

| Year | Core material                                                                                                                                                                 | Additional content                                                                                                                                                                                                      | Material                                                                 |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| 2007 |                                                                                                                                                                               | <ul style="list-style-type: none"><li>• Overview of EMA activities</li><li>• EPAR summary – practical exercises</li><li>• Package leaflet – practical exercises</li></ul>                                               | <ul style="list-style-type: none"><li>• Training book (CD-ROM)</li></ul> |
| 2008 | <ul style="list-style-type: none"><li>• Overview of EMA activities</li><li>• Review of documents<ul style="list-style-type: none"><li>• EPAR</li><li>• PL</li></ul></li></ul> | <ul style="list-style-type: none"><li>• <b>General overview of experience</b><ul style="list-style-type: none"><li>• Reviewers' feedback</li></ul></li><li>• Eudralink</li></ul>                                        | <ul style="list-style-type: none"><li>• Questionnaire</li></ul>          |
| 2009 | <ul style="list-style-type: none"><li>• Overview of EMA activities</li><li>• Review of documents<ul style="list-style-type: none"><li>• EPAR</li><li>• PL</li></ul></li></ul> | <ul style="list-style-type: none"><li>• <b>Reviewers' experience</b><ul style="list-style-type: none"><li>• Patient's perspective on EMA training</li><li>• Evaluation of review of EMA's documents</li></ul></li></ul> | <ul style="list-style-type: none"><li>• Questionnaire</li></ul>          |
| 2010 | <ul style="list-style-type: none"><li>• Overview of EMA activities</li><li>• Review of documents<ul style="list-style-type: none"><li>• EPAR</li><li>• PL</li></ul></li></ul> | <ul style="list-style-type: none"><li>• <b>Safety Communications</b><ul style="list-style-type: none"><li>• Background</li><li>• Patient feedback</li><li>• Practical exercises and examples</li></ul></li></ul>        | <ul style="list-style-type: none"><li>• Training book (CD-ROM)</li></ul> |



## Content of annual training day (2011-2013)

| Year | Core material                                                                                                                                                                                                 | Additional content                                                                                                                                                                                                                                                                                               | Material                                                                 |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| 2011 | <ul style="list-style-type: none"><li>• Overview of EMA activities</li><li>• Review of documents<ul style="list-style-type: none"><li>• EPAR</li><li>• PL</li><li>• Safety communications</li></ul></li></ul> | <ul style="list-style-type: none"><li>• Patient and consumer perspectives on <b>review of product information</b> and training for scientific advice</li></ul>                                                                                                                                                   | <ul style="list-style-type: none"><li>• Training book (CD-ROM)</li></ul> |
| 2012 |                                                                                                                                                                                                               | <ul style="list-style-type: none"><li>• Overview of new <b>Pharmacovigilance legislation</b></li><li>• Introduction of PRAC</li><li>• Risk Management Plans/Post Authorisation Safety Studies</li><li>• Adverse Drug Reaction reporting and Signal Detection</li><li>• Periodic Safety Update Reports)</li></ul> |                                                                          |
| 2013 | <ul style="list-style-type: none"><li>• Overview of EMA activities</li><li>• Review of documents<ul style="list-style-type: none"><li>• EPAR</li><li>• PL</li><li>• Safety communications</li></ul></li></ul> | <ul style="list-style-type: none"><li>• <b>Scientific advice</b> – what is it and how are patients involved</li><li>• <b>Scientific Advisory Groups</b> – what are they and how are patients involved</li><li>• Pharmacovigilance – impact for patients</li></ul>                                                |                                                                          |

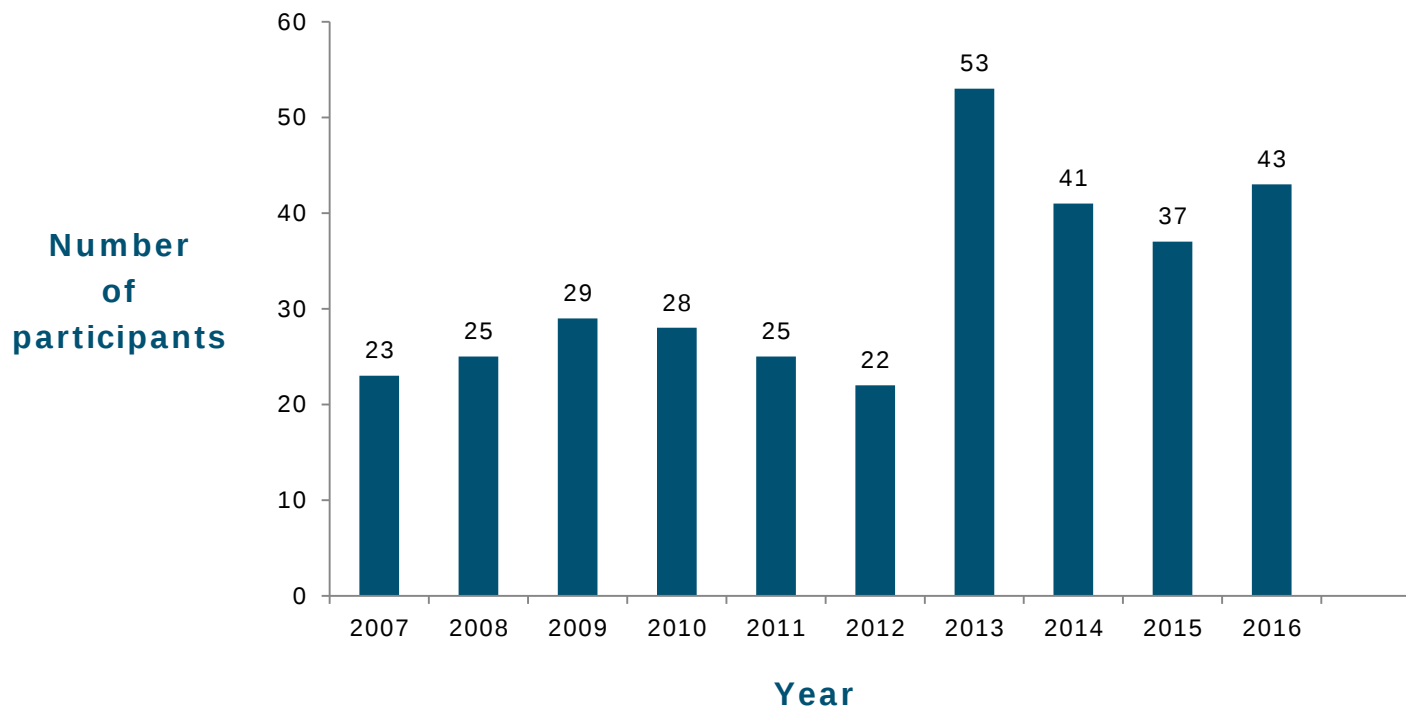


## Content of annual training day (2014-2016)

| Year | Core material                                                                                                                                                                                                                                                                                                       | Additional content                                                                                                     | Material                                                        |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| 2014 | <ul style="list-style-type: none"><li>• Overview of EMA activities</li><li>• Review of documents<ul style="list-style-type: none"><li>• EPAR</li><li>• PL</li><li>• Safety communications</li></ul></li><li>• Scientific Advice/ Scientific Advisory Groups</li><li>• Eudralink/ Declarations of Interest</li></ul> | <ul style="list-style-type: none"><li>• <b>Practical aspects:</b> EMA website/ Declarations of Interest</li></ul>      |                                                                 |
| 2015 | Short presentations on core topics + use of short videos for key topics                                                                                                                                                                                                                                             | <ul style="list-style-type: none"><li>• <b>Hands-on breakout</b> sessions on document review - with debriefs</li></ul> | Documents sent in advance for preparation for breakout sessions |
| 2016 | Short presentations on core topics                                                                                                                                                                                                                                                                                  | <ul style="list-style-type: none"><li>• Hands-on breakout sessions on document review</li></ul>                        | As above and quiz                                               |



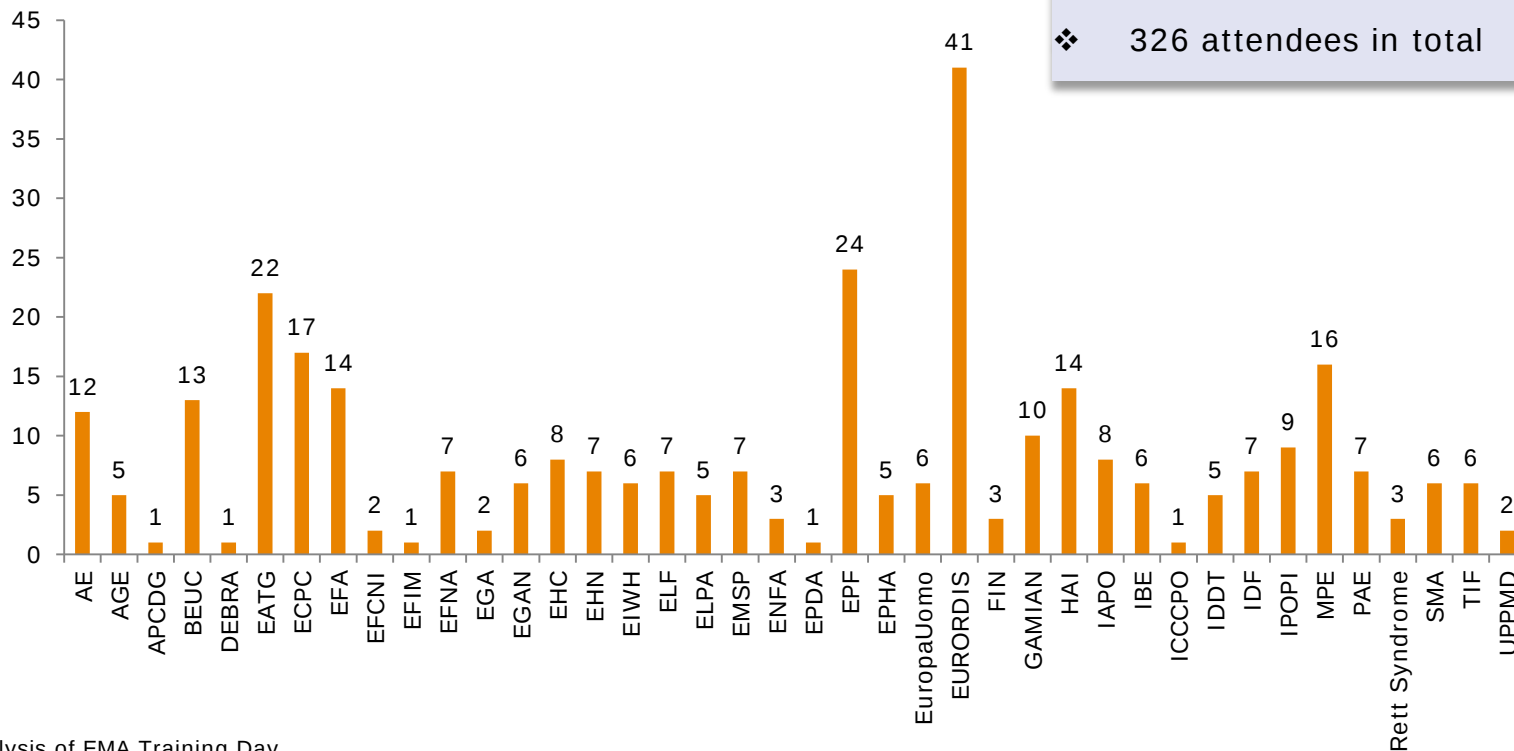
## Total number of participants: per year





# Overall attendance per organisation

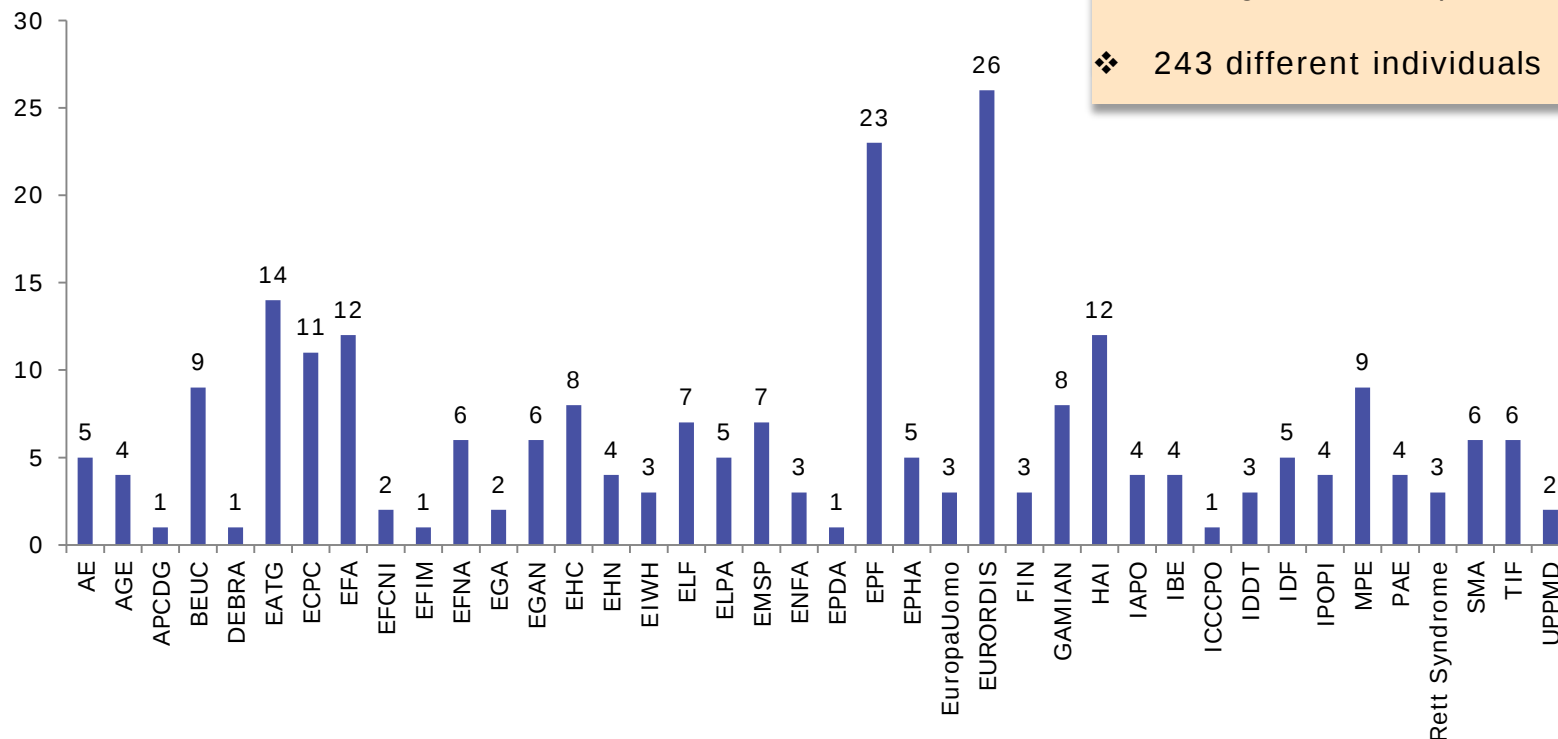
- ❖ 40 organisations (including 1 HCP)
- ❖ 326 attendees in total





# Individual attendance per organisation

- ❖ 40 organisations (including 1 HCP)
- ❖ 243 different individuals



## Outcome of trained participants

Many participants trained in the EMA annual training day have subsequently been involved as:

Members of:

- ❖ Management Board
- ❖ Scientific committees
- ❖ Working parties



Experts in:

- ❖ Scientific advice
- ❖ Scientific advisory groups



❖ Review of documents

❖ Written consultations



## Other training resources at EMA

Dedicated pages on EMA website for Resources and Training for patients and HCP

Links to:

- Training documents
- Recent relevant workshops
- Videos of training days
- Short explanatory videos (EMABasics)
- External training initiatives (links)



| 'EMA Basics' videos                                                  | Related documents                                                                                                                                                                            |
|----------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <a href="#">The European Medicines Agency</a>                        | <a href="#">Presentation - The European Medicines Agency</a>                                                                                                                                 |
| <a href="#">The centralised procedure</a>                            | <a href="#">Presentation - The centralised procedure</a>                                                                                                                                     |
| <a href="#">Involvement of patients</a>                              | <a href="#">Presentation - Involvement of patients</a>                                                                                                                                       |
| <a href="#">The Patients' and Consumers' Working Party</a>           | <a href="#">Presentation - The Patients' and Consumers' Working Party</a>                                                                                                                    |
| <a href="#">EMA video for patient representatives</a>                | <a href="#">Involvement of patient representatives in scientific advice procedures at EMA</a><br><a href="#">Involvement of patient representatives in scientific advisory groups at EMA</a> |
| <a href="#">Pharmacovigilance</a>                                    | <a href="#">Presentation - Pharmacovigilance</a>                                                                                                                                             |
| <a href="#">How EMA works with healthcare professionals</a>          | <a href="#">Presentation - How EMA works with healthcare professionals</a>                                                                                                                   |
| <a href="#">Scientific advice: what to expect and how to prepare</a> | <a href="#">Presentation - Scientific advice: what to expect and how to prepare</a>                                                                                                          |
| <a href="#">Declarations of interests: a practical guide</a>         | <a href="#">Presentation - Declarations of interests: a practical guide</a>                                                                                                                  |
| <a href="#">How patients are involved in the review of documents</a> | <a href="#">Presentation - How patients are involved in the review of documents</a>                                                                                                          |
| <a href="#">What is a European safety referral</a>                   | <a href="#">Presentation - What is a European safety referral</a>                                                                                                                            |

## Future ideas for continued training

- Create more one page 'info sheets' on EMA activities
- Record more EMABasics
- Organise webinars on selected topics
- Investigate tools for creating on-line quizzes
- Create training for young people
- Explore adapted regulatory training for healthcare professionals





# Contact



EMA [Patients and Consumers](#) and [Healthcare professionals](#) webpages

[EMA basics](#)

EMA website: [www.ema.europa.eu](http://www.ema.europa.eu)

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