# eSubmission: Update on all Telematics Projects and the Impact on Regulatory Processes and Companies

## Get informed about the latest status of all EU projects on electronic submission, ranging from eCTD, eAF, CESP, xEVMPD, SPOR, ISO IDMP and ePI

| Type | Date | Language | Location |
|---|---|---|---|
| **Corso online - Limited number** | **20-22-27 October 2020** | **English** | **Online** |

## ABOUT

It is a challenge to keep up-to-date with the details of the EU Regulatory Telematics environment. Besides electronic Common Technical Document (eCTD), many other eSubmission projects are ongoing, including: electronic Application Form (eAF), Common European Submission Plaform (CESP), the EMA Gateway, eXtended Eudravigilance Medicinal Product Dictionary (XEVMPD), ISO Identification of a Medicinal Product (IDMP), SPOR Master Data Management project and electronic Product Information (ePI).

This course will explain the history, current state and outlook of these Telematics projects and impact on Industry. Moreover, it will provide insight on the latest developments, from direct interactions with EMA and National Competent Authorities (NCAs).With all these developments and ongoing activities, this course becomes a 3x3 hour online class and bring you up-to-date with all you need to know with regards to the roadmap and strategy of eSubmission and what you have to consider from an organizational point of view for your company. If you're responsible for Regulatory Affairs, you might not have the time or resources to be aware of all developments, changes and update on the

Telematics roadmap and impact on processes within your organization. To get up-to-date, this course will put the attention on what are the issues to think about for getting ready, including possible Regulatory Information Management (RIM) solutions and company requirements.

## PROGRAMME

**Module 1**: EU Telematics strategy

**Module 2**: Dossier preparation

- eCTD
- Submission (EAF, CESP and Gateway)

**Module 3**: Regulatory Information Management

- xEVMPD
- SPOR
- ISO IDMP

## WHO SHOULD ATTEND

Regulatory Affairs, Regulatory Operations, IT responsible, Pharmacovigilance

### Participant experience

At least 1-2 years' experience in Regulatory Affairs and/or Regulatory Operations.

## TEACHING METHODS

Interactive training on the latest eSubmission projects to create the effective telematics roadmap

## LECTURERS



**Remco Munnik**
**Associate Director at Iperion, The Netherlands**
Remco has a Bachelor degree in Business Administration (Management, Economics and Law). He has over 20 years of experience in Regulatory Affairs, with a special focus on Global submission procedures, electronic submission and regulatory data management. He has been directly involved in the development and roll-out of the EU Telematics environ¬ment and has in-depth knowledge of the systems. Key areas of expertise include Regula¬tory submissions (new MAA to variations), Global eCTD submission, Regulatory Information Management systems (RIM), xEVMPD, ISO IDMP.

## AT THE END OF THE TRAINING, YOU WILL BE ABLE TO

- Understand the current state, latest developments and the future in Telematics area
- Assess the impact the eSubmission roadmap has on your organization
- Prepare yourself and your company for the (near) future, eSubmission requirements

## USEFUL INFORMATION

**Online training – 3 modules**

| | |
|---|---|
| October 20th, 2020 | 2.30 pm – 5.30 pm CEST |
| October 22nd, 2020 | 2.30 pm – 5.30 pm CEST |
| October 27th, 2020 | 2.30 pm – 5.30 pm CEST |

After the registration, you will receive all details about the connection.

**The course will proceed with a minimum number of participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.**

## REGISTRATION FEE

**Early Bird**: **€ 1.320,00\*** (until 29 September 2020)
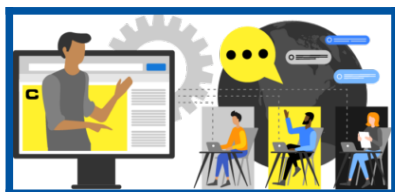
**Ordinary**: **€ 1.420,00\***

**Freelance – Academy – Public Administration\*\***: **€ 792,00\***

\* for Italian companies: +22% VAT

\*\*Early Bird discount not applicable to Freelance – Academy – Public Administration fee

**The fee includes:** tuitions, organizational office assistance, teaching materials and attendance certificate that will be sent after the training via e-mail.

## SEDE DEL CORSO

Online interactive training on Zoom platform.
*LS Academy will provide the access link to the virtual platform a few days before the training.*