Service Concession – ref. EMA/2016/43/RS

Estimated business requirements 2017

	Topic/Module	**Event type** T=Training I=Information Day W=Workshop M=Meeting	**Duration** (in days)	**Key learning objective(s) / further information** (as applicable)	**Stakeholder(s)** 1=Regulators 2=MAHs 3=Sponsors of clinical trials 4=Others	**Competency assessment** YES/NO	**Frequency** A=Annually D=on demand
1	Pharmacovigilance Information Day	I	1	Provide a forum to discuss latest developments in pharmacovigilance	1,2,3,4	No	3xA
2	EU statistics forum	T	1	Discussion of timely topics of mutual theoretical and practical interest to statisticians and clinical trialists; establish a dialogue on issues including EMA guidance development and regulatory science initiatives	1,2,3,4	No	1xA
3	Workshop with NCAs on regulatory procedural aspects	W	1	Provide a forum to identify improvement opportunities in how processes are run for the Network and discuss simplification proposals	1	No	1xA (EMA)
4	PSUR info day	I	1	Present the latest developments from the PSUR roadmap	1,2	No	1xA (EMA)
5	Policy 0070	M	1	Anonymisation, commercial confidential information	2,3,4	No	1xA (EMA)
6	Clinical Trials programme - system training for Member States	I	1	Provide a detailed, end-to-end overview of the system and its interfaces with other systems with a focus on Member State processes; introduce system training tools and materials	1	No	1xA
7	Data Integration programme - system and processes training course for Member States, MAHs, Sponsor of CT and other interested stakeholders	T	3	Understand how to submit, update, nullify and manage entries in the EMA MDM solution; understand how to use relevant API, dashboards and HL7 Messages.	1,2,3,4	Yes	24xA
8	Data Integration programme - Infoday	I	1	Provide a forum to discuss latest developments in the Data Integration Programme	1,2,3,4	No	3xA
9	ICSR reporting *'hands-on'*	T	3	Understand the electronic reporting process in the new EudraVigilance system	1,2,3	Yes	11xA (EMA) 6xA (MSs)
10	ICSR Information Day	I	1	Provide a forum to discuss latest developments in the ICSR format	1,2,3,4	No	2xA
11	ICSR reporting (existing EudraVigilance system) *'hands-on'*	T	3	Understand the electronic reporting process in EudraVigilance (system version 7)	1,2,3	Yes	8XA (EMA)

12	Enpr-EMA	W	2	Workshop of the European network of paediatric research (Enpr-EMA) to provide networking and collaboration with all stakeholders, including patient and parent organisations, network representatives, pharmaceutical industry staff responsible for paediatric studies and regulators	1,2,3,4	No	1xA
13	EMA public workshop on extrapolation of efficacy and safety in medicine development	W	2	Discussion on the need and possibility of developing a framework for extrapolation approaches that are considered scientifically valid and reliable to support medicine authorisation	1,2,3,4	No	1xA

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Estimated business requirements 2018

	Topic/Module	**Event type** T=Training I=Information Day W=Workshop M=Meeting	**Duration** (in days)	**Key learning objective(s) / further information** (as applicable)	**Stakeholder(s)** 1=Regulators 2=MAHs 3=Sponsors of clinical trials 4=Others	**Competency assessment** YES/NO	**Frequency** A=Annually D=on demand
1	Pharmacovigilance "Hot topic"	I	1	Provide a forum to discuss latest developments in pharmacovigilance	1,2,3,4	No	3xA
2	EU statistics forum	T	1	Discussion of timely topics of mutual theoretical and practical interest to statisticians and clinical trialists; establish a dialogue on issues including EMA guidance development and regulatory science initiatives	1,2,3,4	No	1xA
3	Workshop with NCAs on regulatory procedural aspects	W	1	Provide a forum to identify improvement opportunities in how processes are run for the Network and discuss simplification proposals	1	No	1xA (EMA)
4	Policy 0070	M	1	Anonymisation, commercially confidential information	2,3,4	No	1xA (EMA)
5	Clinical Trials programme - system training for Member States	I	1	Provide a detailed, end-to-end overview of the system and its interfaces with other systems with a focus on Member State processes; introduce system training tools and materials	1	No	2xA
6	Clinical Trials programme - system training for Stakeholders	I	1	Provide a detailed, end-to-end overview of the system and its interfaces with other systems with a focus on Sponsor processes; introduce system training tools and materials	3, 4	No	2xA
7	Data Integration programme - system and processes training course for Member States, MAHs, Sponsor of CT and other interested stakeholders	T	3	Understand how to submit, update, nullify and manage entries in the EMA MDM solution; understand how to use relevant API, dashboards and HL7 Messages	1,2,3,4	Yes	24 xA
8	Data Integration programme - Infoday	I	1	Provide a forum to discuss latest developments in the Data Integration Programme	1,2,3,4	No	3 xA
9	ICSR reporting *'hands-on'*	T	3	Understand the electronic reporting process in the new EudraVigilance system	1,2,3	Yes	10xA (EMA) 6xA (MSs)
10	ICSR Information Day	I	1	Provide a forum to discuss latest developments in ICSRs	1,2,3,4	No	2xA

11	Enpr-EMA	W	2	Workshop of the European network of paediatric research (Enpr-EMA) to provide networking and collaboration with all stakeholders, including patient and parent organisations, network representatives, pharmaceutical industry staff responsible for paediatric studies and regulators	1,2,3,4	No	1xA
12	EMA public workshop on extrapolation of efficacy and safety in medicine development	W	2	Discussion on the need and possibility of developing a framework for extrapolation approaches that are considered scientifically valid and reliable to support medicine authorisation	1,2,3,4	No	1xA

Service Concession – ref. EMA/2016/43/RS

Estimated business requirements 2019

	Topic / Module	**Event type** T=Training I=Information Day W=Workshop M=Meeting	**Duration** (in days)	**Key learning objective(s) / further information** (as applicable)	**Stakeholder(s)** 1=Regulators 2=MAHs 3=Sponsors of clinical trials 4=Others	**Competency assessment** YES/NO	**Frequency** A=Annually D=on demand
1	Pharmacovigilance "Hot topic"	I	1	Provide a forum to discuss latest developments in pharmacovigilance	1,2,3,4	No	3xA
2	EU statistics forum	T	1	Discussion of timely topics of mutual theoretical and practical interest to statisticians and clinical trialists; establish a dialogue on issues including EMA guidance development and regulatory science initiatives	1,2,3,4	No	1xA
3	Workshop with NCAs on regulatory procedural aspects	W	1	Provide a forum to identify improvement opportunities in how processes are run for the Network and discuss simplification proposals	1	No	1xA (EMA)
4	Policy 0070	M	1	Anonymisation, commercially confidential information	2,3,4	No	D
5	Clinical Trials programme - system training for Member States	I	1	Provide a detailed, end-to-end overview of the system and its interfaces with other systems with a focus on Member State processes; introduce system training tools and materials	1	No	1xA
6	Clinical Trials programme - system training for Stakeholders	I	1	Provide a detailed, end-to-end overview of the system and its interfaces with other systems with a focus on Sponsor processes; introduce system training tools and materials	3,4	No	1xA
7	Data Integration programme - system and processes training course for Member States, MAHs, Sponsor of CT and other interested stakeholders	T	3	Understand how to submit, update, nullify and manage entries in the EMA MDM solution; understand how to using relevant API, dashboards and HL7 Messages	1,2,3,4	Yes	24 xA
8	Data Integration programme - Infoday	I	1	Provide a forum to discuss latest developments in the Data Integration Programme	1,2,3,4	No	3 xA
9	ICSR reporting *'hands-on'*	T	3	Undestand the electronic reporting process in the new EudraVigilance system	1,2,3	Yes	10xA (EMA) 6xA (MSs)
10	ICSR Information Day	I	1	Provide a forum to discuss latest developments in ICSRs	1,2,3,4	No	2xA

11	Enpr-EMA	W	2	Workshop of the European network of paediatric research (Enpr-EMA) to provide networking and collaboration with all stakeholders, including patient and parent organisations, network representatives, pharmaceutical industry staff responsible for paediatric studies and regulators	1,2,3,4	No	1xA
12	EMA public workshop on extrapolation of efficacy and safety in medicine development	W	2	Discussion on the need and possibility of developing a framework for extrapolation approaches that are considered scientifically valid and reliable to support medicine authorisation	1,2,3,4	No	1xA

Service Concession – ref. EMA/2016/43/RS

Estimated business requirements 2020

	Topic/Module	**Event type** T=Training I=Information Day W=Workshop M=Meeting	**Duration** (in days)	**Key learning objective(s) / further information** (as applicable)	**Stakeholder(s)** 1=Regulators 2=MAHs 3=Sponsors of clinical trials 4=Others	**Competency assessment** YES/NO	**Frequency** A=Annually D=on demand
1	Pharmacovigilance "Hot topic"	I	1	Provide a forum to discuss latest developments in pharmacovigilance	1,2,3,4	No	3xA
2	EU statistics forum	T	1	Discussion of timely topics of mutual theoretical and practical interest to statisticians and clinical trialists; establish a dialogue on issues including EMA guidance development and regulatory science initiatives	1,2,3,4	No	1xA
3	Workshop with NCAs on regulatory procedural aspects	W	1	Provide a forum to identify improvement opportunities in how processes are run for the Network and discuss simplification proposals	1	No	1xA (EMA)
4	Policy 0070	M	1	Anonymisation, commercially confidential information	2,3,4	No	D
5	Clinical Trials programme - system training for Member States	I	1	Provide a detailed, end-to-end overview of the system and its interfaces with other systems with a focus on Member State processes; introduce system training tools and materials	1	No	1xA
6	Clinical Trials programme - system training for Stakeholders	I	1	Provide a detailed, end-to-end overview of the system and its interfaces with other systems with a focus on Sponsor processes; introduce system training tools and materials	3, 4	No	1xA
7	Data Integration programme - system and processes training course for Member States, MAHs, Sponsor of CT and other interested stakeholders	T	3	Understand how to submit, update, nullify and manage entries in the EMA MDM solutionI; understand how to using relevant API, dashboards and HL7 Messages	1,2,3,4	Yes	24 xA
8	Data Integration programme - Infoday	I	1	Provide a forum to discuss latest developments in the Data Integration Programme	1,2,3,4	No	3 xA
9	ICSR reporting *'hands-on'*	T	3	Understand the electronic reporting process in the new EudraVigilance system	1,2,3	Yes	10xA (EMA) 6xA (MSs)
10	ICSR Information Day	I	1	Provide a forum to discuss latest developments in ICSRs	1,2,3,4	No	2xA

11	Enpr-EMA	W	2	Workshop of the European network of paediatric research (Enpr-EMA) to provide networking and collaboration with all stakeholders, including patient and parent organisations, network representatives, pharmaceutical industry staff responsible for paediatric studies and regulators	1,2,3,4	No	1xA
12	EMA public workshop on extrapolation of efficacy and safety in medicine development	W	2	Discussion on the need and possibility of developing a framework for extrapolation approaches that are considered scientifically valid and reliable to support medicine authorisation	1,2,3,4	No	1xA