



30 June 2023
EMA/19987/2022
Administration and Corporate Management Division

Annual list of contract modifications 2022

The European Medicines Agency is required by its Financial Regulation of 1 July 2019 (Article 172 of the general Financial Regulation refers) to publish on its external website a list of modification of contracts as set out in point (c) of article 172(3) of the Financial Regulation and modification of contracts as set out in point (a) and (b) of article 172(3) of the Financial Regulation where the value of the modification is below the threshold laid down in article 175(1) of the Financial Regulation.

Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
A001 to SC05 (FWC EMA/2018/28/PE)	EU PE&PV Research Network (lead: Universiteit Utrecht)	Early safety monitoring of SARS-CoV-2 vaccines in EU Member States	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 30/01/2022 until 31/03/2022
A002 to SC01 (FWC EMA/2018/29/PE)	IQVIA Ltd	Impact of EU label changes fluoroquinolone containing medicinal products for systemic and inhalation use: post-referral prescribing trends	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c.	€ 12,500.00	N/A



Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
A002 to SC01 (FWC EMA/2018/28/PE)	EU PE&PV Research Network (lead: Universiteit Utrecht)	Impact of EU label changes and pregnancy prevention programme for medicinal products containing valproate and related substances: post- referral utilisation and prescribing trends	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 25/02/2022 until 30/04/2022
A003 to SC01 (FWC EMA/2018/28/PE)	EU PE&PV Research Network (lead: Universiteit Utrecht)	Extending duration from 30/04/2022 to 30/06/2022	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 30/04/2022 until 30/06/2022
A002 to SC02 (FWC EMA/2018/28/PE)	EU PE&PV Research Network (lead: Universiteit Utrecht)	Impact of EU label changes and revised pregnancy prevention programme for oral retinoid containing medicinal products: utilisation and prescribing trends	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 25/02/2022 until 30/05/2022
A002 to SC04 (FWC EMA/2018/28/PE)	EU PE&PV Research Network (lead: Universiteit Utrecht)	Change of timelines D3b, D4,D5 and D8. Extending duration to 29/09/2023	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c	N/A	From 30/06/2022 until 29/09/2023

Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
			(without change to the contract value).		
A001 to Service Contract no. EMA/2021/21/LD	Trilateral Research Limited	Provision of data protection expertise to support EMA evaluation committee in the assessment of initial tenders submitted by shortlisted tenderers of the procurement procedure DARWINEU (ref. EMA/2021/08/TD A), and preparation of the DARWINEU Data Protection Impact Assessment on the final offer/solution	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 30/03/2022 until 30/06/2022
A001 to Framework Contract no. EMA/2021/24/SG	McKinsey Solutions SRL	Development of a short-term senior leadership programme, based on workshops and centred around the topic of inspirational collective leadership and strategic transformation	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	N/A
A003 to SC01 (FWC EMA/2018/28/PE)	EU PE&PV Research Network (lead: Universiteit Utrecht)	Impact of EU label changes and pregnancy prevention programme for medicinal products containing	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c	N/A	From 30/04/2022 until 30/06/2022

Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
		valproate and related substances: post-referral utilisation and prescribing trends	(without change to the contract value).		
A003 to SC02 (FWC EMA/2018/28/PE)	EU PE&PV Research Network (lead: Universiteit Utrecht)	Impact of EU label changes and revised pregnancy prevention programme for oral retinoid containing medicinal products: utilisation and prescribing trends	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 30/04/2022 until 30/06/2022
A001 to SC02 (FWC EMA/2018/23/PE)	EU PE&PV Research Network (lead: Universiteit Utrecht)	Impact of EU label changes and regulatory communication on SARS-CoV-2 adenovirus vector vaccines in context of thrombosis with thrombocytopenia syndrome (TTS): risk awareness and adherence	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 04/10/2022 until 04/12/2022
A002 to SC02 (FWC EMA/2018/23/PE)	EU PE&PV Research Network (lead: Universiteit Utrecht)	Extension of timelines for D3 & D4- expiration date 30/05/2023	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 04/12/2022 until 30/05/2023
A002 to SC04 (FWC EMA/2018/29/PE)	IQVIA Ltd	Single-arm studies with historical controls	Article 172 paragraph 3 of the general Financial Regulation –	N/A	From 04/05/2022 until 15/09/2022

Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
		for cancer drug development	Performance and modifications of the contract – subparagraph c (without change to the contract value).		
A003 to SC04 (FWC EMA/2018/29/PE)	IQVIA Ltd	Change of time line D5 and extension of duration of the contract until 30/11/2022	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 15/09/2022 until 30/11/2022
A001 to SC01 (FWC EMA/2018/19/PE)	IQVIA Ltd	Trade-offs between benefits and harms of drugs- A stated preference study with adult cancer patients in Europe	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 04/05/2022 until 04/08/2023
FWC EMA/2018/23/PE	University of Utrecht Consortium	Efficacy and safety studies on medicines, Lot 3	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	N/A
FWC EMA/2018/28/PE	University of Utrecht Consortium	Efficacy and safety studies on medicines, Lot 4	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c	N/A	N/A

Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
			(without change to the contract value).		
A001 to SC01 (FWC OC/EFSA/FIN/2019/01)	PricewaterhouseCoopers PWC EU Services EESV	Business Programme and Project Management, Change Management and Business and Technology Alignment	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	N/A
A001 to SC0025 (FWC OC/EFSA/FIN/2019/01)	Deloitte Consulting & Advisory	Change management maturity scan	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 15/05/2022 until 17/06/2022
A001 to SC001 (FWC EMA/2020/42/DED)	BNP Paribas Real Estate Advisory & Property Management UK Limited	Monitoring of subtenant's fit-out activities at the premises at 30 Churchill Place	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 21/09/2022 until 31/12/2022
A001 to SC183 under DI/07722	Insight Belgium Inc.	Provision of consultancy services required to define a Privileged Access Management governance, vision and roadmap to establish policies,	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 30/06/2022 until 31/07/2022

Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
		procedures and processes.			
A002 to SC001 under OC/EFSA/FIN/2019/01	PricewaterhouseCoopers PWC EU Services EESV	Business Programme and Project Management, Change Management and Business and Technology Alignment	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	N/A
A001 to SC003 under OC/EFSA/FIN/2019/01	PACT Consortium (KPMG Advisory CVBA/SCRL & Bearingpoint France SAS)	Lifecycle Regulatory Submissions Raw Data Project	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph (c).	€ 22,425.00	N/A
A001 to SC002 under OC/EFSA/FIN/2019/01	Business Integration Partners S.p.A & Rhea System	Accounts receivable project	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 28/02/2022 until 28/04/2022
A004 to FWC EMA/2019/06/DED	G4S Security Services B.V.	Provision of security services and security consumables/equipment	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph (b).	N/A	N/A
A001 to SC003 implementing FWC EMA/2019/06/DED	G4S Security Services B.V.	Provision of regular man-guarding services	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the	N/A	N/A

Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
			contract – subparagraph (b).		
A001 to Service Contract no. EMA/2020/01/FI	ING Belgium NV/SA	Provision of banking services for the deposit of surplus funds in euro.	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	N/A
A003 to Service Contract no. EMA/2019/02/FI	ABN AMRO BANK NV	Provision of banking services for day to day operations, more specifically bank accounts and online banking services for making and receiving payments in euro mainly within the SEPA area	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	N/A
A001 to SC028 under OC/EFSA/FIN/2019/01	Deloitte Consulting & Advisory	Extension of duration and completion of further tasks related to initial contract scope (define and implement communication plans, risk register and other artefacts)	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph (c).	€ 11,782.50	From 31/10/2022 until 31/12/2022
A004 to concession contract EMA/2016/43/RS	Drug Information Association Inc., Fort Washington, Basel Branch	Replacement of article II.4 on data protection, and article II.10.1.(c) &(d) on liability; introduction of	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract –	N/A	N/A

Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
		article II.10.(e) on data protection.	subparagraph c (without change to the contract value).		
A001 to SC No. COMM-2019-OP-0029-Lot1-007-C-EMA-GOPA COM under FWC No COMM/2019/OP/0029 – Lot 1	GOPA COM.	Speechwriting project	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 30/12/2022 to 31/05/2023
A001 to SC No. COMM-2019-OP-0029-Lot2-009-C-EMA-E2COMMS under FWC No COMM/2019/OP/0029 – Lot 2	EUROPEAN SERVICE NETWORK & ECORYS EUROPE	EMA extended mandate web updates	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 01/06/2022 to 31/03/2023
A001 to SC01 under EMA/2020/46/TDA /L3.02	CONFIRMS MedUni Vienna	Extension of the SC and change of due dates of the D4 and D5	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c (without change to the contract value).	N/A	From 01/04/2023 until 31/05/2023
A001 to SC01 under EMA/2020/46/TDA /L5.04	DKMA	Extended duration of the SC and added new deliverables D5a and D5b	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c.	€ 31,499.00	from 10/12/2022 until 30/09/2023
A003 to SC01 under	Fraunhofer	D3c and D4 a were added as	Article 172 paragraph 3 of the general Financial	€ 216,000.00	from 17/09/2022

Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
EMA/2020/46/TDA /L1.01		additional deliverables	Regulation – Performance and modifications of the contract – subparagraph c.		to 17/02/2023
A001 to SC02 under EMA/2020/46/TDA /L1.01	Fraunhofer	D3a, D3b and D5a a were added as additional deliverables	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c.	€ 92,000.00	N/A
A001 to SC03 under EMA/2020/46/TDA /L1.01	Fraunhofer	D4a was added as additional deliverables	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c.	€ 41,000.00	N/A
A001 to SC02 (FWC EMA/2018/23/PE)	EU PE&PV Research Network (lead: Universiteit Utrecht)	Extension of timelines D3 and D4- expiration date to 20.11.2022.	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c	N/A	From 04/10/2022 until 04/12/2022
A001 to EMA/2021/17/TDA	University Greifswald	D3a and D3b were added.	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c.	€ 34,999.00	From 04/10/2022 to 04/12/2022
A001 to SC001 EMA/2020/13/TDA	IQVIA Solutions BV	Extend the timelines for deliverables and overall duration of the contract till 22/03/2023	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract –	N/A	From 12/02/2023 until 22/03/2023

Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
			subparagraph c. (without change to the contract value).		
AMD02 to EMA/2020/41/TDA	IQVIA Solutions BV	Start date of HTI database	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c. (without change to the contract value).	N/A	From 12/12/2022 until 22/03/2023
A001 to SC001 FWC/EMA/2020/17/TDA-1	Syneos Health Netherlands B.V.	Extension in duration	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c. (without change to the contract value).	N/A	From 31/01/2023 Until 28/02/2023
A001 to S.C. 011 EMA/2019/15/BD	Syneos Health Netherlands B.V.	Increase in value and extension in duration.	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c.	€ 4,932.57	From 31/01/2023 until 28/02/2023
A001 to SC013-DI/07660	Microsoft	Extension in duration	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c. (without change to the contract value).	N/A	From 31/05/2022 until 30/09/2022
A001 to SC183-DI/07722	Insight Technology	Extension in duration	Article 172 paragraph 3 of the general Financial	N/A	From 31/05/2022

Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
	Solutions Belgium		Regulation – Performance and modifications of the contract – subparagraph (c). (without change to the contract value).		until 30/09/2022
A001 to SC209-DI/07722	Insight Technology Solutions Belgium	Extension in duration	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph (c). (without change to the contract value).	N/A	From 30/06/2022 Until 31/07/2022
A001 to SC225-DI-07722	Insight Technology Solutions Belgium	Extension in duration	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c. (without change to the contract value).	N/A	From 28/02/2022 until 30/06/2022
A001 to SC229 DI/07722	Insight Technology Solutions Belgium	Administrative changes to the contract and its annexes and extension in duration	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c. (without change to the contract value).	N/A	From 30/04/2022 until 31/05/2022
A001 to SC281 DI/07722	Insight Technology Solutions Belgium	Extension in duration	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract –	N/A	N/A

Contract no.	Name of contractor	Subject	Legal basis	Modification Value	Increase of Duration
			subparagraph c. (without change to the contract value).		
OC/EFSA/PTT/2015/01 SC024 A001	JV CANCOM-PIRONET	Increase in value and extension of duration	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph c.	€ 45,988.53	From 31/12/2022 until 31/03/2023
A001 to SC001 DI/07926	PwC - Sopra Steria Consortium	Extension in duration	Article 172 paragraph 3 of the general Financial Regulation – Performance and modifications of the contract – subparagraph (c). (without change to the contract value).	N/A	From 31/12/2022 until 28/02/2023