

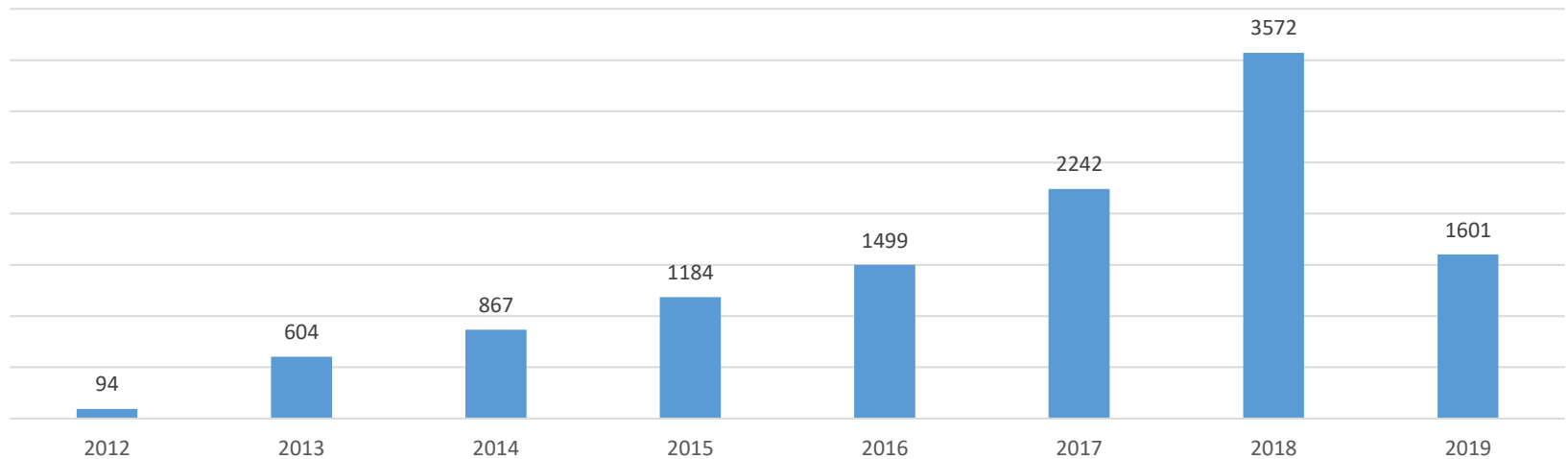
# IPCAA, Ethical MedTech

# Code National Transposition Status – Overview

Country	National Association	Status	Comments
Austria	Austromed	yes	AGM on the 29 March 2017. DS not allowed.
Baltics	MedTech Baltics	To be determined	New Member. Transposition is planned during 2019.
Belgium	BeMedTech	To be determined	Positive board decision to ban DS in 2016. Most likely implementation by 2020, but AGM decision pending.
Croatia	Cromed	To be determined	New Member
Cyprus	SAAIK	Yes	Approved by AGM in October 2018, Code fully into force as of 1st January 2019
Czech Republic	CzechMed	Yes	Transposition in March 2018
	CZEDMA	Yes	Approved by AGM in April 2017, effective January 2018
Denmark	Medicoindustrien	Yes	Approved in 22 March 2018, DS ban in 1 January 2019
	Dialab	To be determined	The Board is informed about the Code
Finland	Sai Lab	yes	Approved on 14 December 2017, DS banned as of 1st January 2019
France	Snitem	To be determined	Discussions ongoing. A best practice workshop took place in December 2018
	SIDIV	To be determined	Discussions ongoing. A best practice workshop took place in December 2018
Germany	BVMed	Yes (Code not binding)	Board decision Oct. 2017 - Addendum to Article 8 Continued Medical Education, Section 2, No. 2 b; BVMed Code
	VDGH	N/A	No plans for formal transposition but proactive promotion of the Code internally and externally
	Spectaris	Yes (Code not binding)	AGM approved new Code on 28 Sept. 2017; in effect as of 1st January 2018
Greece	SIEV	yes	Transposition of MTE Code approved on the 22 June 2017, enter into force 1 January 2018
Hungary	AMDM	yes	Approval for the Code in April 2018. Implementation as of 1st of June 2018
	HIVDA	yes	Transposition in 2017, DS banned as of 1st January 2019
Ireland	Irish Medtech Association	yes	Transposition in 2017, Code in full force as of 2018
	IMSTA	yes	Transposition in 2017, Code in full force as of 2018
Italy	Assobiomedica	yes	Transposition in 2018. DS banned as of 1st January 2019. Transparency in 2021
Middle East	MECOMED	yes	Phase out of direct sponsorship as of January 2018. Transparency in 2019
Norway	MedTek Norge	N/A	Agreement with stakeholders, no transposition needed. Alignment with MTE Code already the case
	LabNorge	N/A	Agreement with stakeholders, no transposition needed. Alignment with MTE Code already the case
Poland	POLMED	yes	Adoption by AGM in 2017; 2018 in force
	MedTech Polska	yes	Adoption by AGM in 2017; 2018 in force
Portugal	APORMED	yes	AGM approved, implementation in July 2018
	APIFARMA	yes	Transposition as of 1.1.2018
Romania	AFPM	Ongoing	AGM approval on 14.02.2018. Transposition with small modifications to be approved during 2018, awaiting information
Russia	IMEDA	Ongoing	Analysis of MTE Code ongoing (translation available). DS not allowed by law
Slovakia	SK-MED	yes	Transposition with small adaptation. 1.2.2018
	SEDMA	yes	Transposition as of 1.1. 2018
Slovenia	SLO-MED	yes	Code fully into force as of 1.1.2018
	SIEDMA	yes	Code fully into force as of 1.1.2018
Spain	FENIN	yes	Board approval on 20.12.2016, DS banned as of 1.1.2018
Sweden	Swedish Medtech	N/A	Agreement with stakeholders, no transposition needed. Alignment with MTE Code already the case
	Swedish Labtech	N/A	Agreement with stakeholders, no transposition needed. Alignment with MTE Code already the case
Switzerland	Swiss MedTech	yes	New Code went into force in June 2017; direct sponsorship ban in force starting 1 January 2018
	SVDI	To be determined	
The Netherlands	NEFEMED	To be determined	Code implementation to be re-discussed in 2019
	FHI	To be determined	Code implementation to be re-discussed in 2019
	DIAGNED	To be determined	Code implementation to be re-discussed in 2019
Turkey	Arted	Ongoing	Transposition to be voted in January 2019 AGM, entry into force 1st January 2020
UK	ABHI	yes	Transposition already started, new Code in force as of January 2017. Phase out DS 1.1.2019
	BIVDA	yes	Board decision in December 2016; Code in full force as of January 2018

# CVS in numbers

Total number of submissions - January 2019



	2013	2014	2015	2016	2017	2018	2019
Total submissions	604	867	1184	1499	2242	3572	1601 (Jan '19)
Increase		43%	36%	21%	49%	59%	



# Third Party Procedure Training - Form

Category of venue (e.g. hotel, museum, conference centre)

OFFICE

City/Town \*

Brussels

## Event Information

Name of the event \*


Enter a name

Therapeutic area

Allergology and Immunology

Event type \*

Third-party procedure training

Event start date  \*

dd-mm-yyyy

Please note that you have selected the Third Party Procedure Training (TPPT) category for your event. We have recently introduced additional qualifying criteria for such events: therefore, you will notice that the submission form has been modified to integrate more information on:

**The set-up of the event:** the event should be a stand-alone one meaning not organised alongside a Third Party Educational Event. If it is the case, please select Third Party Educational Event in the drop down menu.

**The structure of the scientific programme:** we require documented evidence that the scientific programme features 50% of theoretical sessions and 50% of practical sessions with at least 2/3 of the programme being dedicated to hands-on activities. Please fill in the form accordingly.

**The event venue:** the hands-on sessions of TPPT are typically organised in either a clinical environment or in places suitable for or set up to simulate medical procedures.

**The size of the event:** the total number of participants per station

OK



**Ethical MedTech**

MedTech Europe compliance portal

# Third Party Procedure Training - Form

Date		Session Name	Theoretical Session Duration (mins)		Practical Session Duration (mins)		Hands-on Session Duration (mins)		Hospitality Duration (mins)	
2019 1 JUL	MON	Session 1 - Title	30	⬆️⬆️	-	⬆️⬆️	-	⬆️⬆️	-	⬆️⬆️
		Session 2 - Title	-	⬆️⬆️	40	⬆️⬆️	-	⬆️⬆️	-	⬆️⬆️
		Session 3 - Title	-	⬆️⬆️	-	⬆️⬆️	50	⬆️⬆️	-	⬆️⬆️



# Guidelines for NAs on establishing a CVS system

## Recommendations

- 🌀 National Associations can establish local assessment systems to review national events.
- 🌀 National Associations should seek legal advice on establishing a national assessment systems (eg: for compliance with competition laws)
- 🌀 Alignment on the assessed criteria: it is recommended for NAs to maintain similar criteria as CVS Europe to ensure maximum convergence in the way events are assessed.
- 🌀 National Associations (NAs) need to establish a local Compliance Panel which role will be to oversee the system management, hear appeals on decisions made and hear complaints on Code infringements.
- 🌀 Enforce strict submission deadlines.
- 🌀 Have some flexibility by allowing a correction notice period to event organisers for events that present non-compliant aspect.
- 🌀 Keep history/archive of all documents that were used during the evaluation process.