

# **Ethical MedTech Webinar**

## **Training for event organisers and sponsors**

***10 November 2021 from 11.00 to 12.00 (CET)***

Clarisse Aillet, EthicalMedTech  
Myriam Invidia, EthicalMedTech

# Agenda and training objectives

---

Current situation

---

Quick reminder of the rationale of CVS & e4ethics

---

Event submission : Mandatory requirements

---

Event submission form & necessary documentation

---

Criteria : focus on *hospitality / registration fees*

---

# Housekeeping

This training session will be recorded for educational purposes and posted on EthicalMedTech website.

For questions, please send us an email and we will address them in writing.

[Clarisse.aillet@ethicalmedtech.eu](mailto:Clarisse.aillet@ethicalmedtech.eu)

[Myriam.Invidia@ethicalmedtech.eu](mailto:Myriam.Invidia@ethicalmedtech.eu)

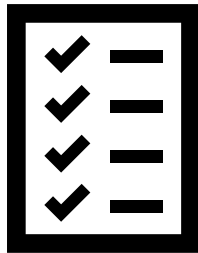
# Current situation

Post Covid landscape : when it is not always about the science

## Surge in non-compliant criteria

Late submissions

Incomplete submissions



Reorganisations

More events

# Rationale behind CVS and e4ethics

# Safeguard industry reputation and harmonise assessments

Public  
perception

Regulators  
perception

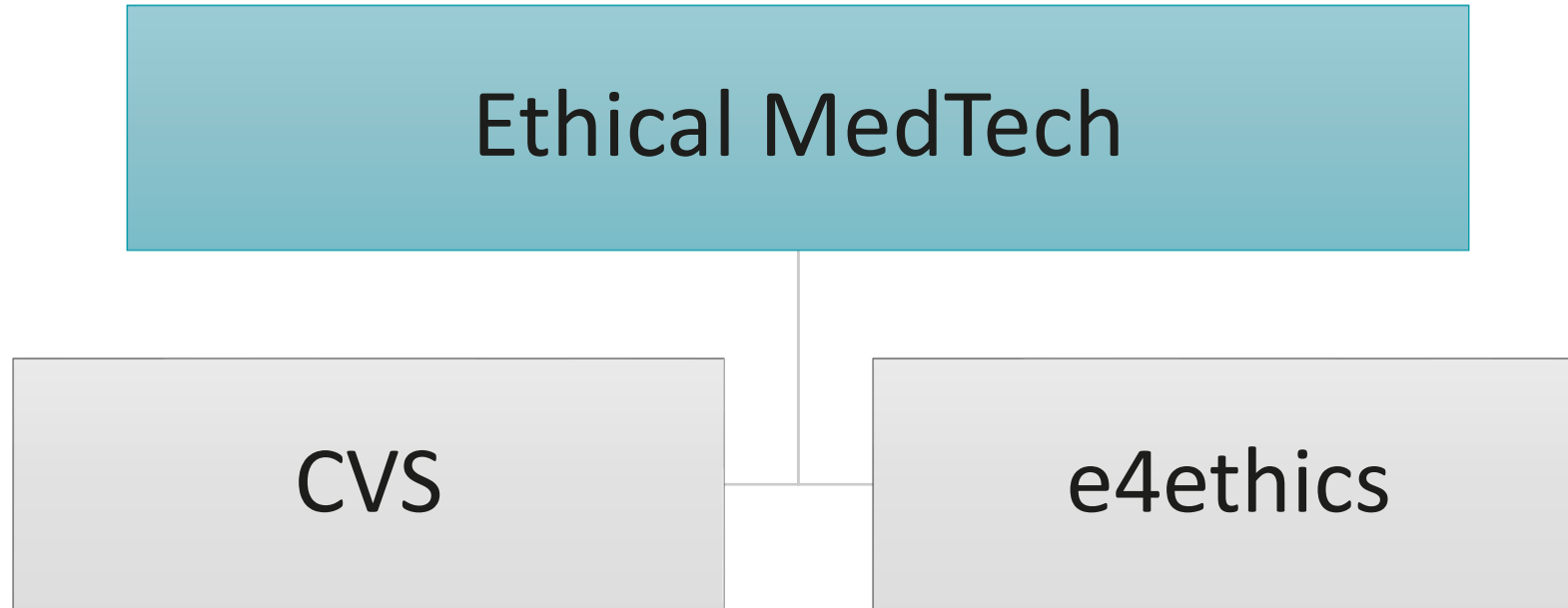
Reduce risk  
for companies

Harmonise  
assessments

Appropriate  
sponsoring

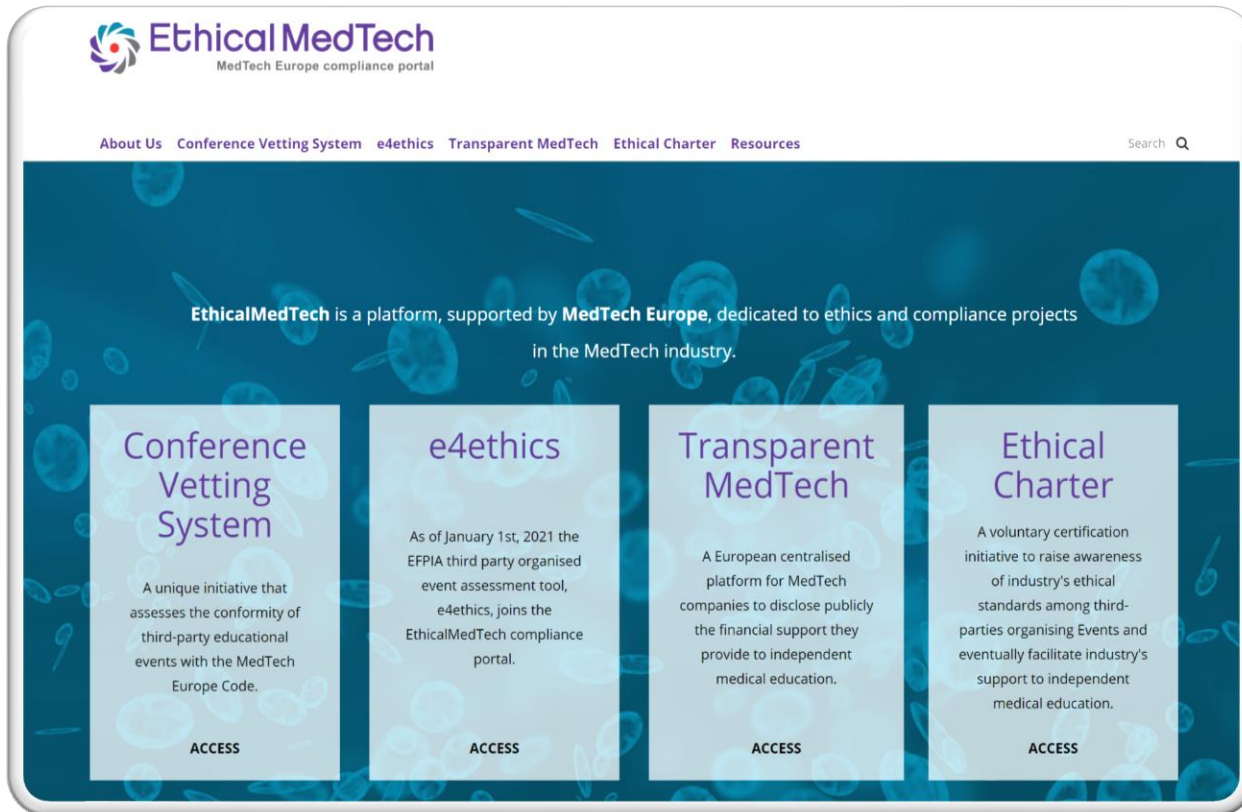
Preserve  
reputation

# A unique compliance approach in the Healthcare industry





# Independent EMT Team & Compliance Panel



# Main features of the common submission platform

---

Online submission, proactive and mandatory

---

Strict deadlines to ensure viability of the system

---

No submission possible by Compliance Officers EthicalMedTech

---

Pre-clearance allowing early submissions

---

Special procedure for late submissions

---

Appeal only possible after final status decision

---

# Event submission : Mandatory requirements

# What type of events should be submitted?



## MANDATORY & BINDING

**Regular + Hybrid events**

**No financial support if final non-compliant status**

# What type of events should be submitted?

Voluntary submission for virtual events

Virtual events = 100% fully online (participants)

Simple publication in calendar / sponsors' rules

# Rules and guidelines for events submissions

## LATE SUBMISSIONS

- 75 days deadline
- New automatic system rejection
- Request for expedited assessment
- Waiver not always granted
- No right to appeal

## INCOMPLETE SUBMISSIONS

- 35 days deadline
- Causes huge delay
- Submission may end up with incomplete submission/ not assessed status

## CORRECTION NOTICE

- 10 days to solve the problem
- Not a final status
- Event could become compliant if corrective measures

## APPEAL

- Within 10 days of final status decision
- Addressed to Compliance Panel Chair
- Last resort decision

# All parties may check directly if event was submitted

## ONLINE CALENDAR CHECK

CVS and e4ethics Events Calendar

Compliant Correction notice Not compliant Provisionally compliant To be reviewed Virtual event Not assessed

« < > » March 2021 CHOOSE MONTH MONTH WEEK

Mon	Tue	Wed	Thu	Fri	Sat	Sun
1	2	3	4	5	6	7
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice International ECMO Network Meeting and Virtual Scientific Series II German-Russian Teleconference on Endocrinology and Diabetology Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series SPINAL DEGENERATIVE PATHOLOGY ONLINE COURSE						
+4 more	+4 more	+12 more	+20 more	+30 more	+22 more	+8 more
8	9	10	11	12	13	14
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice International ECMO Network Meeting and Virtual Scientific Series II German-Russian Teleconference on Endocrinology and Diabetology Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series						
+8 more	+9 more	+13 more	+22 more	+34 more	+25 more	+10 more
15	16	17	18	19	20	21
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice International ECMO Network Meeting and Virtual Scientific Series II German-Russian Teleconference on Endocrinology and Diabetology Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series						
+6 more	+8 more	+10 more	+22 more	+25 more	+23 more	+8 more
22	23	24	25	26	27	28
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice International ECMO Network Meeting and Virtual Scientific Series II German-Russian Teleconference on Endocrinology and Diabetology Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series						
+12 more	+18 more	+25 more	+29 more	+29 more	+16 more	+10 more
29	30	31	1	2	3	4
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice International ECMO Network Meeting and Virtual Scientific Series II German-Russian Teleconference on Endocrinology and Diabetology Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series						
+10 more	+9 more	+9 more	+14 more	+14 more	+10 more	+5 more
5	6	7	8	9	10	11
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice International ECMO Network Meeting and Virtual Scientific Series II German-Russian Teleconference on Endocrinology and Diabetology Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series SPINAL DEGENERATIVE PATHOLOGY ONLINE COURSE						
+3 more	+5 more	+14 more	+21 more	+27 more	+20 more	+7 more

SUBMIT A CONFERENCE SEARCH FOR EVENT

Check  
EMT

# To sponsors: Event not submitted ? YOU can do it 😊

## NO SUBMISSION WITHOUT PRIOR CALENDAR CHECK

# SUBMIT

Register first to be able to submit an Event

### CVS and e4ethics Events Calendar

Compliant Correction notice Not compliant Provisionally compliant To be reviewed Virtual event Not assessed

March 2021 CHOOSE MONTH MONTH WEEK

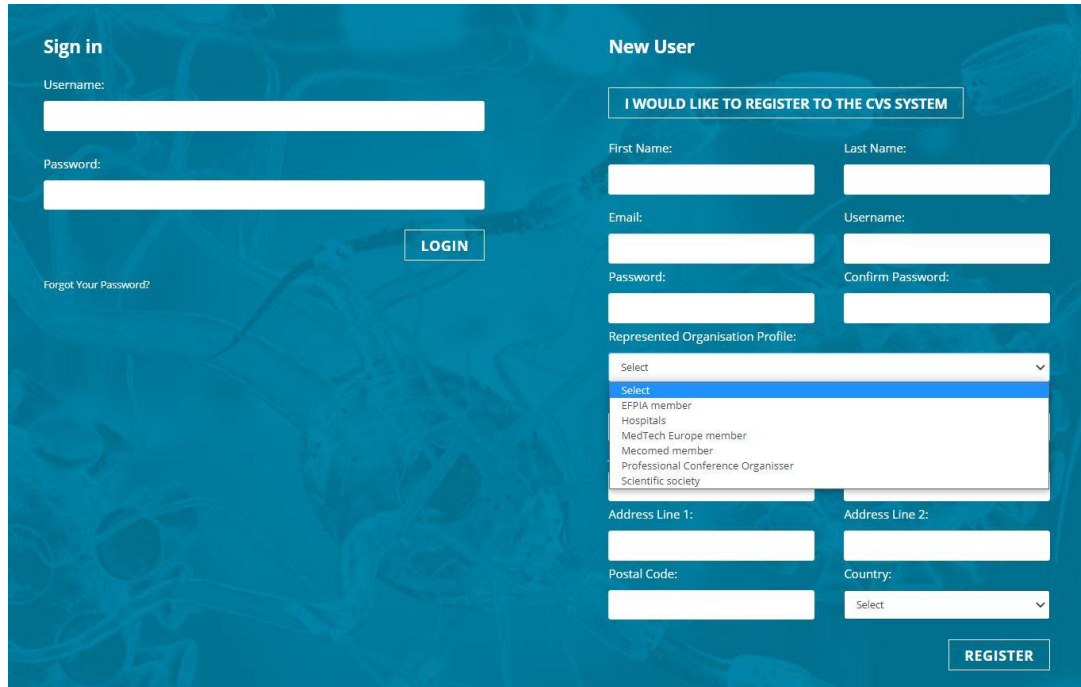
Mon	Tue	Wed	Thu	Fri	Sat	Sun
1	2	3	4	5	6	7
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice International ECMO Network Meeting and Virtual Scientific Series IX German-Russian Teleconference on Endocrinology and Diabetology Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series SPINAL DEGENERATIVE PATHOLOGY ONLINE COURSE						
+4 more	+4 more	+12 more	+20 more	+30 more	+22 more	+8 more
8	9	10	11	12	13	14
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice International ECMO Network Meeting and Virtual Scientific Series IX German-Russian Teleconference on Endocrinology and Diabetology Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series						
+8 more	+9 more	+13 more	+22 more	+34 more	+25 more	+10 more
15	16	17	18	19	20	21
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice International ECMO Network Meeting and Virtual Scientific Series IX German-Russian Teleconference on Endocrinology and Diabetology Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series						
+6 more	+8 more	+10 more	+22 more	+25 more	+23 more	+8 more
22	23	24	25	26	27	28
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice International ECMO Network Meeting and Virtual Scientific Series IX German-Russian Teleconference on Endocrinology and Diabetology Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series						
+12 more	+18 more	+25 more	+29 more	+29 more	+16 more	+10 more
29	30	31	1	2	3	4
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice International ECMO Network Meeting and Virtual Scientific Series IX German-Russian Teleconference on Endocrinology and Diabetology Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series SPINAL DEGENERATIVE PATHOLOGY ONLINE COURSE						
+10 more	+9 more	+9 more	+14 more	+14 more	+15 more	+5 more
5	6	7	8	9	10	11
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice International ECMO Network Meeting and Virtual Scientific Series IX German-Russian Teleconference on Endocrinology and Diabetology Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series SPINAL DEGENERATIVE PATHOLOGY ONLINE COURSE						
+3 more	+5 more	+14 more	+21 more	+27 more	+20 more	+7 more

SUBMIT A CONFERENCE SEARCH FOR EVENT



# Submission form

# When submitting an event - select the right option



The image shows a web interface with two main sections: 'Sign in' and 'New User'.

**Sign in:**

- Username:
- Password:
- [Forgot Your Password?](#)
- [LOGIN](#)

**New User:**

[I WOULD LIKE TO REGISTER TO THE CVS SYSTEM](#)

First Name:  Last Name:

Email:  Username:

Password:  Confirm Password:

Represented Organisation Profile:

- Select
- Select
- EPPIA member
- Hospitals
- MedTech Europe member
- Medcomed member
- Professional Conference Organiser
- Scientific society

Address Line 1:  Address Line 2:

Postal Code:  Country:

[REGISTER](#)

**All fields in submission form must be completed, especially correct contact details for Event Organiser** to ensure automatic status notifications and emails sent by the platform can be delivered

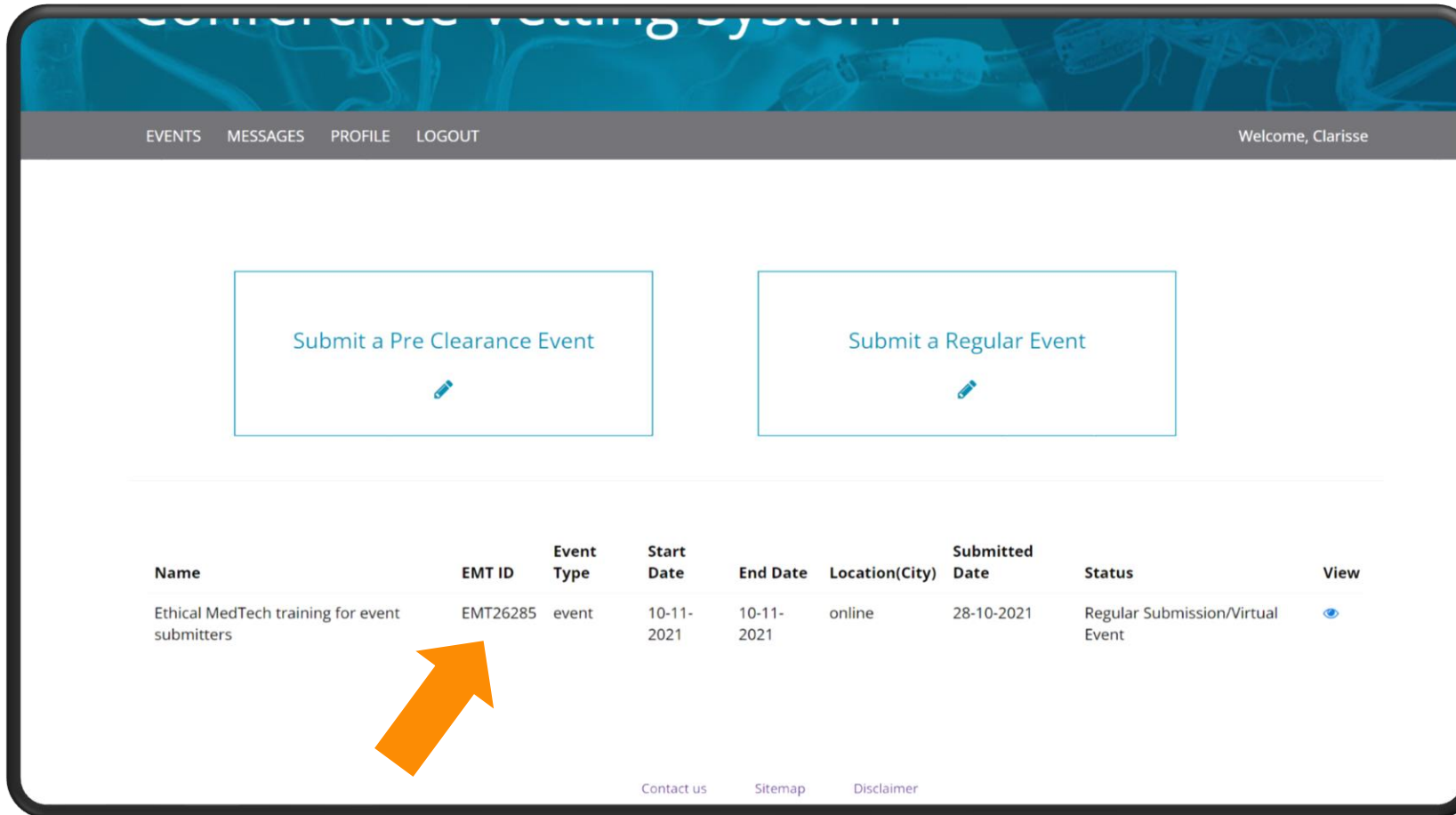
# Systematic upload of documents via the platform

The screenshot displays a registration form for the MedTech Europe compliance portal. The form is divided into several sections:


- Organiser details:** Includes fields for 'Name(s) of organiser(s)', 'Organiser email \*', 'Proposed accommodation (Include http:// for URL)', 'Scientific programme (Include http:// for URL)', and 'Event registration package (fee & benefits for all category of participants, include http:// for URL)'. Each URL field includes a placeholder example: 'e.g. http://www.ethicalmedtech.eu'.
- Contact details:** Includes fields for 'Name(s) of contact(s)' and 'Event website URL (Include http://)' with a placeholder example: 'e.g. http://www.ethicalmedtech.eu'.
- Information on delegates:** Contains two dropdown menus. The first asks 'Will the event be attended by Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area?' with a 'Yes' option selected. The second asks 'Do you anticipate that attending Healthcare Professionals will come from more than one country covered in the scope of Medtech Europe?' with a 'Yes' option selected.
- Appendices/links:** Includes a section for 'Supporting documents/Mulifile upload' with a file selection button labeled 'Sélect. fichiers' and the text 'Aucun fichier choisi'. Below this is a checkbox labeled 'I have read and understood: The MedTech Europe Code of Ethical Business Practice'.

An orange arrow points to the 'Supporting documents/Mulifile upload' section, highlighting the document upload functionality.

# User account - where to find EMT reference

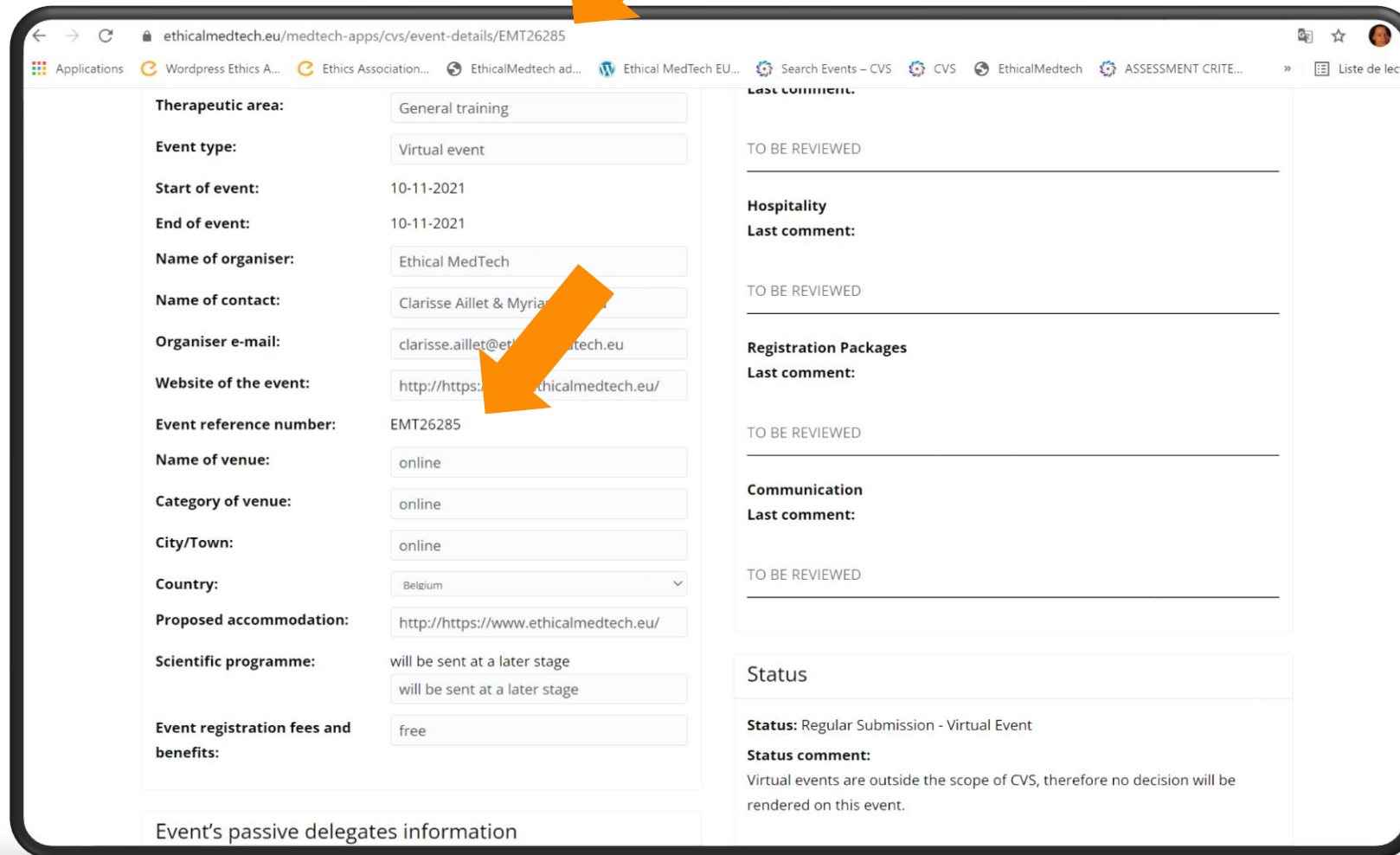


The screenshot displays a user account interface for the 'conference voting system'. The top navigation bar includes links for EVENTS, MESSAGES, PROFILE, and LOGOUT, along with a welcome message 'Welcome, Clarisse'. Below the navigation bar, there are two main action buttons: 'Submit a Pre Clearance Event' and 'Submit a Regular Event', each accompanied by a small icon of a pencil. A horizontal line separates these buttons from a table of submitted events. The table has columns for Name, EMT ID, Event Type, Start Date, End Date, Location(City), Submitted Date, Status, and View. An orange arrow points to the 'EMT ID' column of the first row, which contains the value 'EMT26285'.

Name	EMT ID	Event Type	Start Date	End Date	Location(City)	Submitted Date	Status	View
Ethical MedTech training for event submitters	EMT26285	event	10-11-2021	10-11-2021	online	28-10-2021	Regular Submission/Virtual Event	

At the bottom of the interface, there are links for 'Contact us', 'Sitemap', and 'Disclaimer'.

# EMT reference is key



The screenshot shows a web browser displaying the event details for EMT26285. The URL in the address bar is `ethicalmedtech.eu/medtech-apps/cvs/event-details/EMT26285`. An orange arrow points to the `EMT26285` part of the URL. Another orange arrow points to the `Event reference number: EMT26285` field in the form.

<b>Therapeutic area:</b>	General training
<b>Event type:</b>	Virtual event
<b>Start of event:</b>	10-11-2021
<b>End of event:</b>	10-11-2021
<b>Name of organiser:</b>	Ethical MedTech
<b>Name of contact:</b>	Clarisse Aillet & Myriam
<b>Organiser e-mail:</b>	clarisse.aillet@ethicalmedtech.eu
<b>Website of the event:</b>	<a href="http://https://ethicalmedtech.eu/">http://https://ethicalmedtech.eu/</a>
<b>Event reference number:</b>	EMT26285
<b>Name of venue:</b>	online
<b>Category of venue:</b>	online
<b>City/Town:</b>	online
<b>Country:</b>	Belgium
<b>Proposed accommodation:</b>	<a href="http://https://www.ethicalmedtech.eu/">http://https://www.ethicalmedtech.eu/</a>
<b>Scientific programme:</b>	will be sent at a later stage
<b>Event registration fees and benefits:</b>	free

Event's passive delegates information

**Last comment:**

TO BE REVIEWED

**Hospitality**

**Last comment:**

TO BE REVIEWED

**Registration Packages**

**Last comment:**

TO BE REVIEWED

**Communication**

**Last comment:**

TO BE REVIEWED

**Status**

**Status:** Regular Submission - Virtual Event

**Status comment:**

Virtual events are outside the scope of CVS, therefore no decision will be rendered on this event.

# Alignment between Sponsors / Organisers

Align and agree in writing on WHO MAKES THE EVENT SUBMISSION – to avoid duplicates and delays



ALIGN

Any potential change of date, of geographic location, or venue must be communicated urgently to the Ethical MedTech team, as it may have an impact on assessment decision

# COMING SOON – FLAG & FOLLOW EVENT STATUS



FOLLOW

You will be able to select event by event if you wish to be informed of status changes (opt-in)

CHECK

SUBMIT

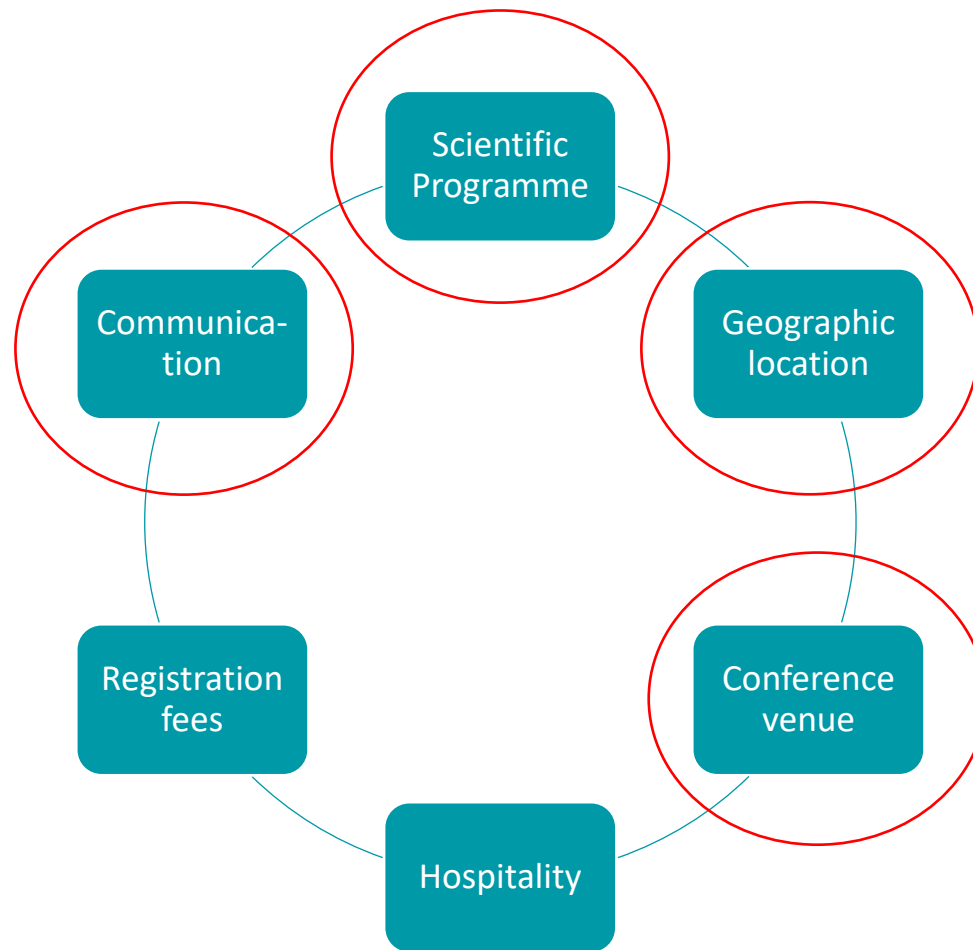
ALIGN

FOLLOW



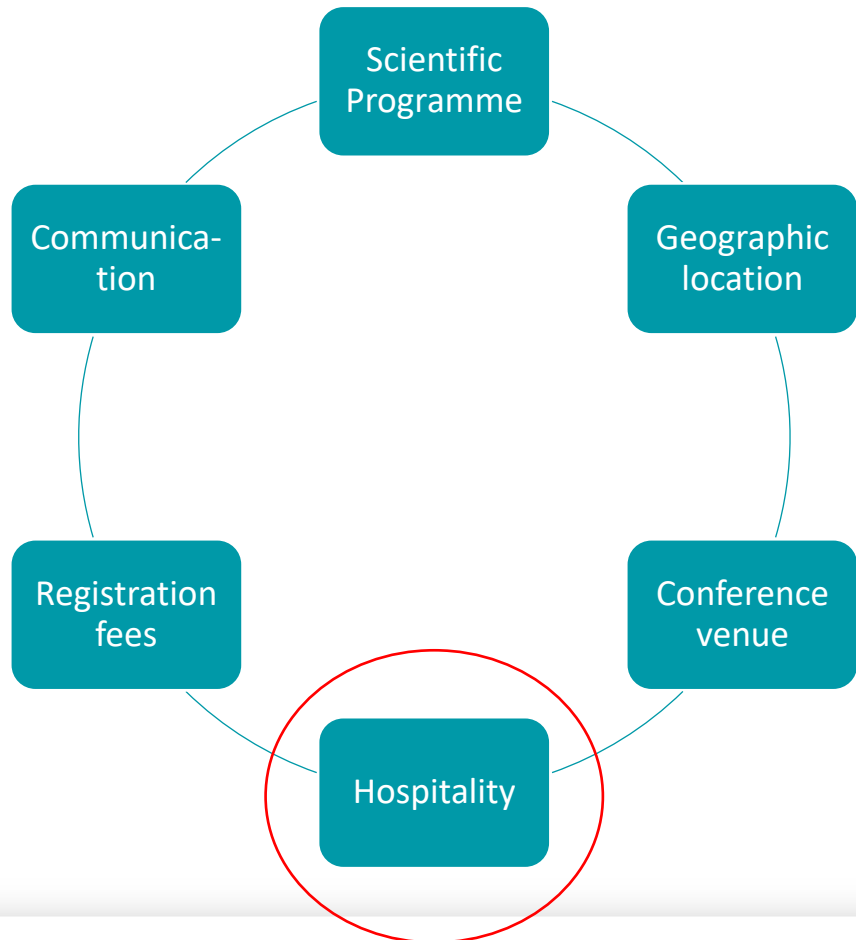
Criteria : focus on hospitality  
& registration fees

# 6 criteria assessed with same weight



**26 000 soumissions**  
**13 octobre 2021**

# What is covered by hospitality criteria?



# Hospitality - reminder

Hospitality covers **accommodation, meals/breaks and receptions** (opening reception, gala dinner, networking event, get-together, etc).

**HOSPITALITY ≠ ENTERTAINMENT**

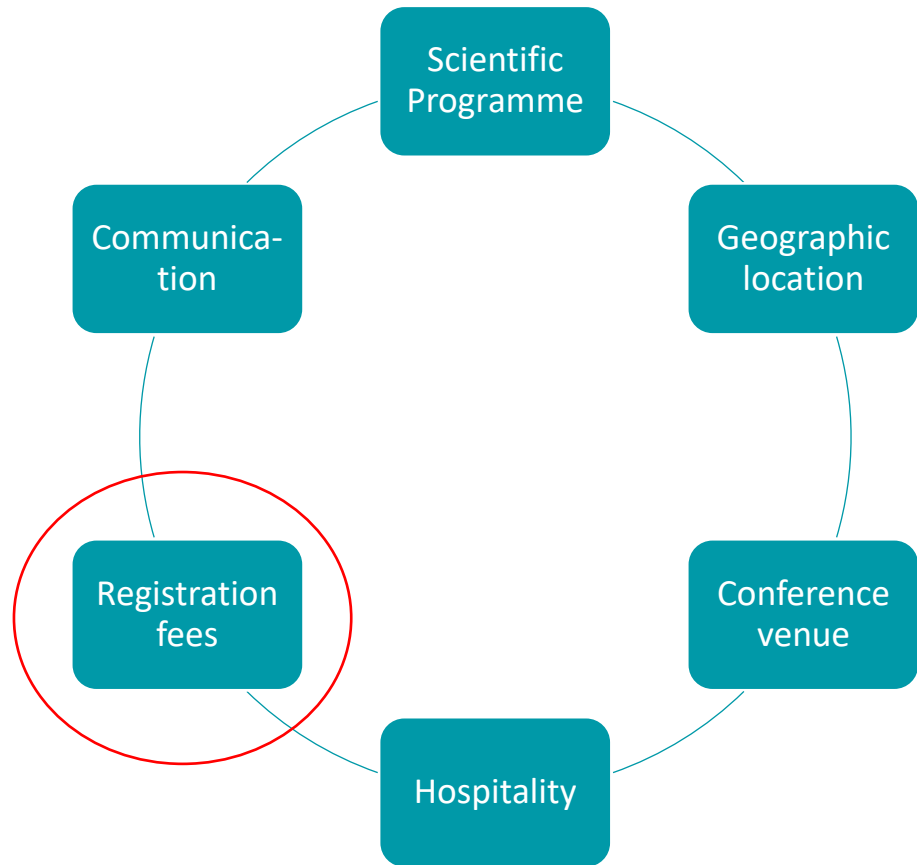
**Our team only looks at the hospitality that is covered by registration fees.**

## Hospitality – one clear example

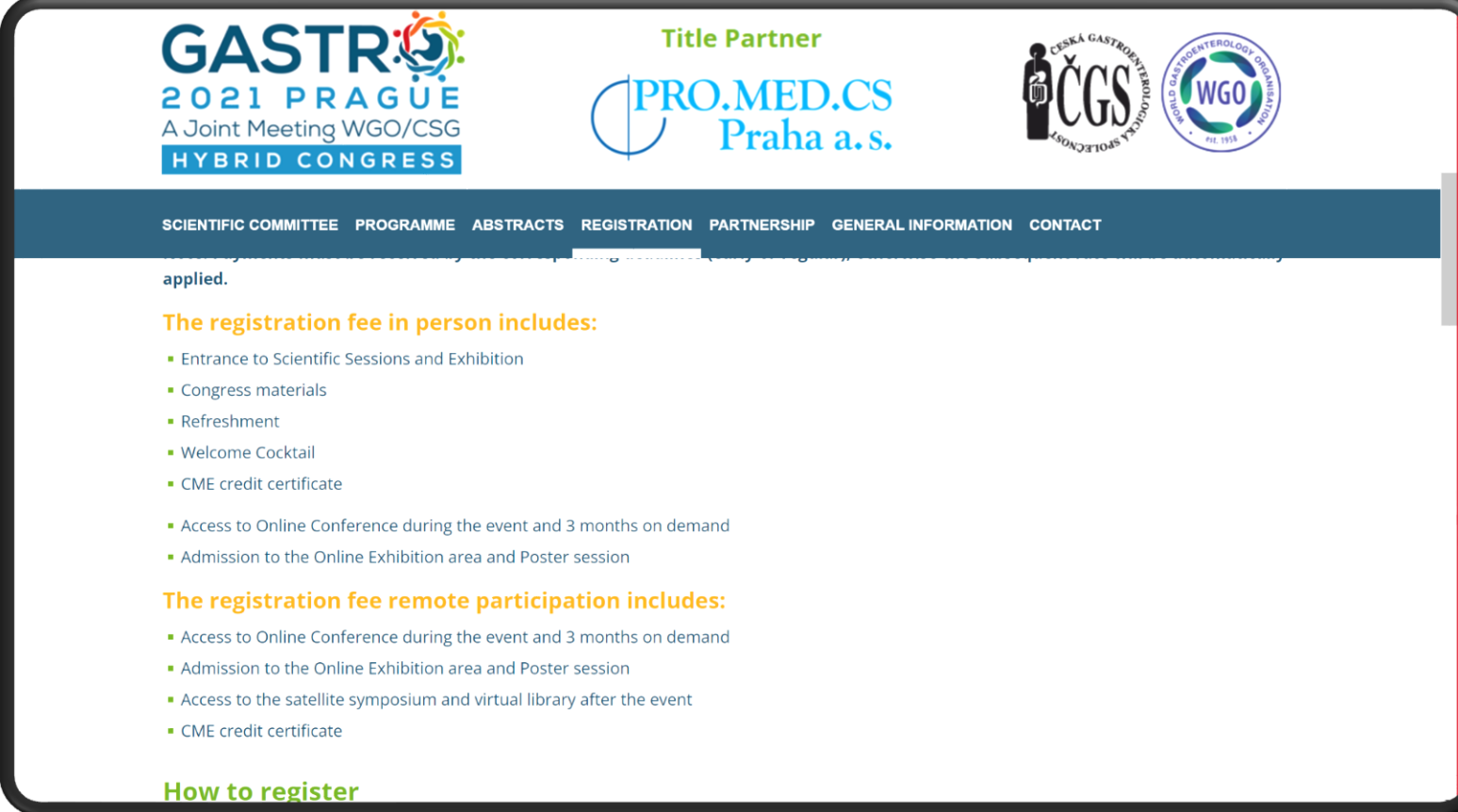
*Dear Ladies and Gentlemen, here you will find our main program booklet with all information about the program of the xxxxxxxx Congress (from p. 10) and also the contents of the registration packages (p. 7).*

*Hospitality will be provided on a self-pay basis (managed by in-house caterers at the venue) at the bistro station xxxxxx located xxxxxx. An entertainment program is not planned.*

# What is meant by registration fees ?



# How to clarify what registration fees precisely cover?



The screenshot displays the website for GASTR 2021 PRAGUE, a joint meeting of WGO and CSG. The header includes the event logo, the title partner PRO.MED.CS Praha a.s., and logos for the organizing societies, CSG (Ceska Gastroenterologicka Spolecnost) and WGO (World Gastroenterology Organisation). A navigation bar lists various sections, with 'REGISTRATION' highlighted. The main content area details the registration fee inclusions for in-person and remote participation.

**GASTR 2021 PRAGUE**  
A Joint Meeting WGO/CSG  
HYBRID CONGRESS

**Title Partner**  
**PRO.MED.CS**  
Praha a.s.

**CSG** **WGO**

SCIENTIFIC COMMITTEE PROGRAMME ABSTRACTS **REGISTRATION** PARTNERSHIP GENERAL INFORMATION CONTACT

applied.

**The registration fee in person includes:**

- Entrance to Scientific Sessions and Exhibition
- Congress materials
- Refreshment
- Welcome Cocktail
- CME credit certificate
- Access to Online Conference during the event and 3 months on demand
- Admission to the Online Exhibition area and Poster session

**The registration fee remote participation includes:**

- Access to Online Conference during the event and 3 months on demand
- Admission to the Online Exhibition area and Poster session
- Access to the satellite symposium and virtual library after the event
- CME credit certificate

**How to register**

# Back-up slides on events status



# What are the possible status of an Event?

## Final Status

- Compliant (in green): the Event presents no liability for EFPIA/MedTech Europe members and is eligible to receive appropriate support from members
- Not Compliant (in red): a flag is raised. Different forms, as per the respective Codes, of support to an Event should be suspended, withdrawn, or cancelled as per the agreement with the Event organiser
- Not assessed (in grey): the Event submitted is not eligible to be assessed under CVS/e4ethics. For example, strictly National Events are not eligible
- Virtual Events (in yellow): the Event was submitted voluntarily and there will be no formal assessment conducted. But the Compliance Officers will check and confirm by publishing this status on the Calendar that the Event is a 100% online/virtual with no in-person HCP attendance

# What are the possible status of an Event?

## Intermediary status

- To be reviewed (in **purple**): the Event submitted is in the review process and no decision has yet been rendered by the Compliance Officers.
- Provisionally Compliant (in **blue**): means the most challenging criteria of an Event, namely the geographic location and conference venue, have been assessed compliant. The Compliance Officers are waiting for additional information from the submitting party to finalise the assessment.
- Correction Notice (in **orange**): means that a non-compliant aspect of an Event has been identified by the Compliance Officers. A communication has been sent to the organisers with a proposed correction. The organiser have 10 days to implement that correction and provide proof of the change to the Compliance Officers to avoid having their Event assessed as not compliant.

# Virtual Events

**Virtual Third Party Organised Educational Event (“Virtual Event”) are not subject to the e4ethics.**

But we recommend to submit them anyway in the platform to keep track and visibility (yellow category in the Calendar). No CVS decision

**Companies are free to sponsor or not these virtual events according to their internal guidelines.**

**Sponsors may not require from PCO a CVS / e4ethics assessment or decision on virtual events.**

Thank you for your attention!

<https://www.ethicalmedtech.eu/>

Clarisse Aillet [clarisse.aillet@ethicalmedtech.eu](mailto:clarisse.aillet@ethicalmedtech.eu)

Myriam Invidia [myriam.invidia@ethicalmedtech.eu](mailto:myriam.invidia@ethicalmedtech.eu)