Transparent MedTech User Manual

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TUE 12:30 PM

MedTech Europe from diagnosis to cure



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1. The Transparent MedTech platform

a. Introduction

Transparent MedTech is the central database where Companies¹ are to publish the Educational Grants they provide to Healthcare Organisations (HCOs) based or registered in the MedTech Europe Geographical Area²³, in accordance with the <u>MedTech Europe Code of Ethical Business Practice</u> ("the Code").

This also includes any financial allocation to medical education provided to for-profit entities such as Professional Conference Organisers (PCOs).

b. Scope: Educational Grants

Educational Grants are defined in the Code (Part IV: Glossary) as follows:

• <u>Educational Grants</u>: means provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.

Educational Grants are further regulated in Chapter 4, Section 3 of the Code. In particular, the Code notes that Educational Grants can be provided for the following (<u>non-exhaustive</u>) purposes:

- a. Support for Third Party Organised Educational Events, including:
 - 1. Support for HCP Participation at Third Party Organised Educational Events
 - 2. Support for Third Party Organised Educational Events
- b. Scholarships and Fellowships
- c. Grants for Public Awareness Campaigns

¹ MedTech Europe Members or Members of National Associations that are member of MedTech Europe and have decided to use TransparentMedTech as their transparency system.

² MedTech Europe Geographic Area includes the countries in the European Economic Area as well as those countries where Member Associations are located (Switzerland, Turkey, Russia and the countries covered by Mecomed, the Middle East and Africa Association).

³ The countries covered by Mecomed are not within the scope of the disclosure obligation for the time being and until further notice.



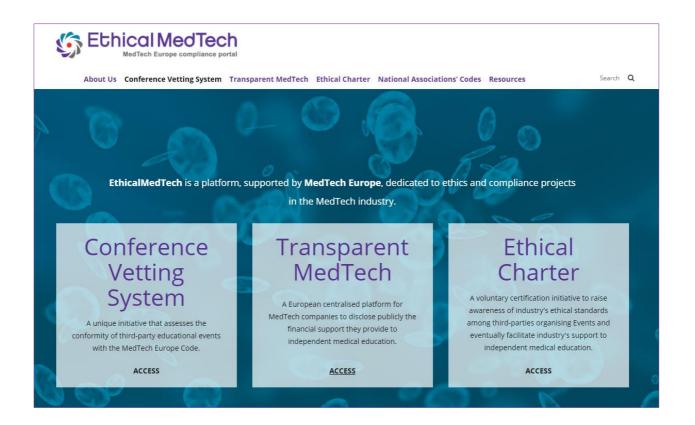
c. Format of the publication

Educational Grants are disclosed in Transparent MedTech under two different categories:

- 1. Support for Third Party Organised Educational Events (which includes points a.1 and a.2 above) and,
- 2. Any other Educational Grant (including points b and c)

d. Accessing the system

Transparent MedTech, as one of the MedTech Europe Ethics and Compliance initiative, is hosted on <u>www.ethicalmedtech.eu</u>





2. Company Account(s)

a. Account management

Companies are free to choose the internal arrangement they will use to disclose the Educational Grants, meaning that the system allows for reporting of Educational Grants at European level (with one single account), or the creation of as many accounts as necessary for subsidiaries, branches, or other dependent entities.

Each Company will nonetheless need to create **one** Master Company which will be approved by the MedTech Europe Secretariat.

Once this Master Company has been created and approved, Companies are free to create Subsidiary Companies (please note this is a generic name for accounts dependent on the Master Company, it is not meant to have any legal implication).

Based on the experience built during the first years of the system, we recommend using a single account for disclosure, as it provides for a simpler procedure, easier monitoring and clearer reporting, but the possibility to report under multiple accounts remains available.

<u>Important</u>: If you had an account under the previous version of the system, you do not need to create a new account, the accounts have been converted to the new system.

You will need to input a new password the first time you log in.

b. Account structure:

There are two types of Companies:

- Master Companies (the parent or umbrella account)
- Subsidiary Companies (depending on the parent company)

There is only one type of User Account. Users can be linked to multiple companies (both Master and Subsidiary companies).

Users have "roles" in each company they are linked to. There are two roles:

- Manager (has all the rights, i.e, creating declarations and managing the company and the users linked to it)
- Encoder (can only create declarations)



c. User Account creation procedure

Ideally, the company should create a dedicated e-mail address for transparency purposes. This will make it easier to transfer the account if there is an eventual change of roles in the organisation and will also help further anonymise interactions related to TransparentMedTech (such as replying to enquiries by third parties about declarations). This account can be for instance <u>transparency@company.com</u> or <u>eu-transparency@company.com</u>.

User Account creation steps:

Navigate to the main page of Transparent MedTech and click on "Company access", on the right top corner of the screen.

Transparent MedTech	Your search here	٩	Company access
Welcome to t	he MedTech Europe	e transparency platforr	n
	Use the search form located above to	get started.	

In the next screen, click on "Register"

Email	
Password	Ø
Forgot password?	Login
Don't have an account yet?	Register

In the following screen, please enter the requested information to create a User Account and click on "Register".



In the "Companies" field, you can <u>choose</u> to enter the name of the Company or Companies you want to associate this User Account with, even if the Company does not yet exist, and therefore does not appear in the autocomplete. The system will create a blank company with that name, and you will need to edit the details afterwards from the Company page. <u>You can also create a new company afterwards</u>.

<u>Important</u>: If you want to link this User Account to an <u>existing</u> Company, you need to select the company or companies (master or subsidiary) at this stage. <u>See letter g).</u>

It is recommended to use the generic transparency account mentioned at the beginning of this section to create this account.

First name	
Last name	
Email	
Phone	
Password	ø
Companies	
	Register

Once you have clicked on "**<u>Register</u>**", you will see the following screen:

Please hold on...

Your account was successfully created, but it still needs to be validated by the system administrator. You will be able to access the system once your account is validated. If you need more information, please contact transparency@medtecheurope.org.

You can contact the MedTech Europe Secretariat (ethics@medtecheurope.org or

<u>transparency@medtecheurope.org</u>) to let us know that you have registered your User Account, and you are awaiting activation. We will only activate a User Account once we verify the account has been created by the right person within the organisation.



Once we activate your account you will receive the following e-mail:

тм	Transparent MedTech <transparency@medtecheurope.org></transparency@medtecheurope.org>
	Hello,
	Your account was successfully validated by the system administrator. You are now able to access the system. If you need more information, please contact transparency@medtecheurope.org
	Go to Transparent Medtech

You can now log into the system using the combination of the registered email address and password in the Company Access page:

Email tr	mt2@test.com	
Password	•••••	Ø
Forgot passv	vord?	Login
Don't have a	n account yet?	Register



Once logged in, the main Company Site page looks like this:

Transparent MedTech	Your search here	٩	ଡ ନ G
	What do you want to do?		
	+ Add a new declaration		
	← Import multiple declarations via a CSV file		
	III Manage declarations		
	Manage beneficiaries		
	Manage companies		

d. Company creation & editing procedure

As mentioned in the previous section, there are two ways to create a company (both Master Companies and Subsidiary Companies), directly during the User Account creation procedure, or after it. In either case, you need to click on "Manage Companies" in the main menu.



If you already added the name of your company during the User Account creation procedure above, you will see the Company already under the "Manage Companies" screen:

Tra	ansparent MedTech			Your search here			۹ (G
	Add a new company								
	Name 🍦	Zip code 💲	Country ≑	Contact first name 🌩	Contact last name 🍦	Your role 👙	Your status 💲		
	Test Account 2020					Manager	Active	Edit Manage users	
								< 1 >	



By default, you will be assigned the role of the Company Account manager, but this can be changed by clicking in the "Manage Users" button.

You will need to edit the company and introduce all the required information, to do this click on "<u>Edit</u>". It will take you to this screen:

Name T	est Account 2020	
Zip code		
Country		
Contact firs	t name	
Contact las	t name	
Contact em	ail	
Contact ph	one	
Contact UR	L	
Parent co	mpany	~
		Save

Please fill all the fields and click on Save

This process also works for subsequent edits to the company.



If you did not create the company while creating your user, you simply need to click on Add a new company This will take you to this screen:

Name	
Zip code	
Country	
Contact first name	
Contact last name	
Contact email	
Contact phone	
Contact URL	
Parent company	~
	Save

Fill all the fields and click on Save .

Important: In either case, please note the Zip Code field is only intended to facilitate searches, you can choose not to use any actual Zip Code, but it is recommended.

The MedTech Europe Secretariat will validate the creation of the Company.



e. Subsidiary Company creation procedure

To create a Subsidiary Account, you will first need to click on Anage companies Then click on Add a new company

Follow the same procedure as described above for the Master Company, but make sure to select the right Parent Company under the Parent Company field as shown below, and then click on Save

Contact URL		Test Account 2020	×
Parent company	^		Save
Test Account 2020	Save		

You will now see the subsidiary listed in the 📅 Manage companies

menu.

Add a new company									
Name ≑	Zip code	Country 🗘	Contact first 🖕	Contact last name	Your role	Your status 👙			
Test Subsidiary 2020			NA	NA	Manager	Waiting admin validation	View		
Test Account 2020	1111		Pablo	Trolo	Manager	Active	Edit Manage users View subsidiaries		
							< 1 ;		

Once the MedTech Europe secretariat activates this subsidiary, you will be able to Edit it and manage its users.

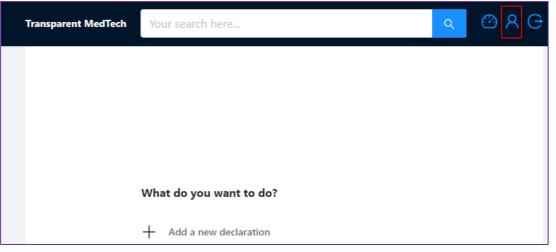
Add a new company										
Name 💠	Zip code	Country \$	Contact first name	÷	Contact last name	4	Your role	Your status	*	
Test Subsidiary 2020			NA		NA		Manager	Active		Edit Manage users
Test Account 2020	1111		Pablo		Trolo		Manager	Active		Edit Manage users View subsidiaries

To delete a Subsidiary Account, please contact us in ethics@medtecheurope.org or transparency@medtecheurope.org).



f. Account management & Adding existing User Accounts to existing Companies

The user account details can be changed by clicking on the R icon that can be found on the top right part of the screen.



Change any details that need amending, including requesting access as a User to additional companies by adding them in the last line.

First name	
Last name	
Email	
Phone	
Test Subsidiary 2020 \times	Test Account 2020 \times
	Save

After all changes are introduced, please do not forget to click on Save

If you are requesting changes in the Companies line, please contact <u>ethics@medtecheurope.org</u> or <u>transparency@medtecheurope.org</u>) for validation, or wait until the current manager of the Company you are requesting access to validates your request.



g. Creating additional User accounts for reporting and managing Subsidiary Companies

Additional accounts for users to access the system and report can be created by following the same procedure outlined in the "<u>User Account creation procedure</u>" section, <u>but making sure to select the</u> <u>Company to which the new account will be linked to</u>:

First name	ertert	
Last name	ertertetr	
Email tes	stest@test.com	
Phone		
Password		Ø
test sub		
test sub		
Test Subsidia	ary 2020	\checkmark
	Test Subsidiary 2020	

The manager of the account to which the new user needs to be added needs to activate the account. To do this, the manager needs to go to Manage companies then click on "Manage Users" in the relevant Company line;

Add a new compar	ny									
Name 🌲	Zip code [⊕]	Country 🖨	Contact first name	÷	Contact last name	÷	Your ÷	Your status	÷	
Test Subsidiary 2020			NA		NA		Manager	Active		Edit Manage users
Test Account 2020	1111		Pablo		Trolo		Manager	Active		Edit Manage users View subsidiaries
										< 1



And then click on "Activate":

Manage company users			
First Last name name Email ≑	Role 🌲	Status 💠	
	Manager	Active	
	Encoder	Waiting manager validation	Activate Make manager
			< 1 >

You can also make this user the manager of that company by clicking on "Make manager".



3. Disclosing

a. Beneficiary Management

To manually disclose Educational Grants, you need to first add a beneficiary.

To do that, first click on	 Manage beneficiaries 	
In the next screen, click c	Add a new beneficiary	
Fill the fields and click on	Save	
	Add new beneficiary	
	Name	
	Address	
	Zip code	
	City	
	Country	
	Unique identifier	
	Save	

All the beneficiaries linked to a company can be found in the O Manage beneficiaries screen.

sparent MedTech	1	Your search her	e			٩	<i>(</i> ଅ ମ
Add a new bene	eficiary						
Filter beneficiarie	25				Q		
Name 💠	Address	Zip code 💠	City 💲	Country 👙	Unique identifier 💠		
Test	Rue du Test 123	123456	Testville	France	FR123456789	Edit	emove
Test	Rue du Test 123	123456	Testville	France	FR123456789	Edit	emove
Test	Rue du Test 123	123456	Testville	France	FR123456789	Edit	emove
testingtesting	teste	1234	test	Bosnia	354345354	Edit	emove
Test	Rue du Test 123	123456	Testville	Italy	IT123456789	Edit	emove
test recipient	rtest address	1234	Brussels	Austria	123456	Edit	emove
Test	Rue du Test 123	123456	Testville	France	FR123456789	Edit	emove
Test	Rue du Test 123	123456	Testville	France	FR123456789	Edit	emove



Important: Beneficiaries can be removed only if they are not linked to any declaration, and any edition of a beneficiary will affect any disclosure in which they have been used.

Once the beneficiary has been added, it can be used for multiple reporting years.

		b.	Individu	al disclo	osure
To create a declaration Then on Add a new decl Complete the fields and	aration		declarations	in the ma	in menu.
]	Add new declar	ation			
	Company			\sim]
	Beneficiary			\vee	
	Year				
	Amount 0			G)
	Currency			\sim	
	Support to Edu	ıcational Ev	ents	\sim	
	Comment				
				Save	

Notes:

- You can select the company under which you would like to report in the drop-down "Company" menu. A list of the companies associated to the user will appear.
- The same for the beneficiaries.
- In case you would like to use a currency not in the drop down menu, please contact the Secretariat.
- Please make sure to use a dot as the decimal separator, not the comma.

The declaration will now be shown in the 🗉 Manage declarations page.



c. Bulk disclosure

To disclose the information for several HCOs at once, click on E Import multiple declarations via a CSV file in the main menu.

A specific excel template must be used. This template can be downloaded from the abovementioned menu by clicking on "Download sample"⁴.

	~
⊥ Click to upload	

Proceed filling the Excel template with the information.

Notes:

- The only optional field is the "Object" field.
- The fields "Currency", "Country" and "Educational Grant Type" require specific formats for the information in them.

You can find the correct format for these fields in the "CSV Formatting" list in <u>Annex I</u> of this Manual.

• To introduce decimals, please use the dot, not the comma

Save the file and upload it in the	Import multiple declarations via a CSV file	page, by clicking in the
"Click to upload" button.		

⁴ Please note this template has changed from the first version of the platform.



Test	Account 2020	~	
	上 Click to upload		
	占 Download sample		

Any mistakes in the form will be highlighted in the "Error in the CSV" area. Please fix them, save the updated file, and re-upload it.

d. Declaration editing

All the declarations linked to companies were your user has a management or reporter ("enconder") role will appear under the E Manage declarations page.

You can sort them by clicking on the arrows next to each column, and you can also use the search bar on top. The search function will capture anything in the declarations, i.e, year, beneficiary, company, etc.

To edit any declaration, just click on it in the list, introduce the changes and save it. You can also desactivate the declarations simply by clicking on "disable", that way they will not be shown publicly.



CURRENCIES

BAM - Bosnia Mark BGN - Bulgarian Lev CAD - Canadian Dollar CHF - Swiss Franc CNY - Yuan CZK - Czech Koruna DKK - Danish Krone

COUNTRIES

[AF] - Afghanistan [AL] - Albania [DZ] - Algeria [AS] - American Samoa [AD] - Andorra [AO] - Angola [AI] - Anguilla [AQ] - Antarctica [AG] - Antigua and Barbuda [AR] - Argentina [AM] - Armenia [AW] - Aruba [AU] - Australia [AT] - Austria [AZ] - Azerbaijan [BS] - Bahamas [BH] - Bahrain [BD] - Bangladesh [BB] - Barbados [BY] - Belarus [BE] - Belgium [BZ] - Belize [BJ] - Benin [BM] - Bermuda [BT] - Bhutan [BO] - Bolivia [BA] - Bosnia and Herzegovina [BW] - Botswana

Annex I: CSV formatting.

- EUR Euro GBP - Poud Sterling GEL - Georgian Lari HRK - Croatian Kuna HUF - Hungarian Forint ISK - Icelandic Krona JPY - Yen NOK - Norwegian Krone
- PLN Polish Zloty RON - Fourth Romanian leu RUB - Russian Ruble SEK - Swedish Krona TRY - Turkish Lira UAH - Ukranian hryvnia USD - Us Dollar

[CR] - Costa Rica

[BV] - Bouvet Island [BR] - Brazil -[BQ] British Antarctic Territory [IO] - British Indian Ocean Territory [VG] - British Virgin Islands [BN] - Brunei [BG] - Bulgaria [BF] - Burkina Faso [BI] - Burundi [KH] - Cambodia [CM] - Cameroon [CA] - Canada [CT] - Canton and Enderbury Islands [CV] - Cape Verde [KY] - Cayman Islands [CF] - Central African Republic [TD] - Chad [CL] - Chile [CN] - China [CX] - Christmas Island [CC] - Cocos [Keeling] Islands [CO] - Colombia [KM] - Comoros [CG] - Congo - Brazzaville [CD] - Congo - Kinshasa [CK] - Cook Islands

[HR] - Croatia [CU] - Cuba [CY] - Cyprus [CZ] - Czech Republic [DK] - Denmark [DJ] - Djibouti [DM] - Dominica [DO] - Dominican Republic [NQ] - Dronning Maud Land [DD] - East Germany [EC] - Ecuador [EG] - Egypt [SV] - El Salvador [GQ] - Equatorial Guinea [ER] - Eritrea [EE] - Estonia [ET] - Ethiopia [FK] - Falkland Islands [FO] - Faroe Islands [FJ] - Fiji [FI] - Finland [FR] - France [GF] - French Guiana [PF] - French Polynesia [TF] - French Southern Territories [FQ] - French Southern and Antarctic Territories



[GA] - Gabon [GM] - Gambia [GE] - Georgia [DE] - Germany [GH] - Ghana [GI] - Gibraltar [GR] - Greece [GL] - Greenland [GD] - Grenada [GP] - Guadeloupe [GU] - Guam [GT] - Guatemala [GG] - Guernsey [GN] - Guinea [GW] - Guinea-Bissau [GY] - Guyana [HT] - Haiti [HM] - Heard Island and McDonald Islands [HN] - Honduras [HK] - Hong Kong SAR China [HU] - Hungary [IS] - Iceland [IN] - India [ID] - Indonesia [IR] - Iran [IQ] - Iraq [IE] - Ireland [IM] - Isle of Man [IL] - Israel [IT] - Italy [JM] - Jamaica [JP] - Japan [JE] - Jersey [JT] - Johnston Island [JO] - Jordan [KZ] - Kazakhstan [KE] - Kenya [KI] - Kiribati [KW] - Kuwait [KG] - Kyrgyzstan

[LA] - Laos [LV] - Latvia [LB] - Lebanon [LS] - Lesotho [LR] - Liberia [LY] - Libya [LI] - Liechtenstein [LT] - Lithuania [LU] - Luxembourg [MO] - Macau SAR China [MK] - Macedonia [MG] - Madagascar [MW] - Malawi [MY] - Malaysia [MV] - Maldives [ML] - Mali [MT] - Malta [MH] - Marshall Islands [MQ] - Martinique [MR] - Mauritania [MU] - Mauritius [YT] - Mayotte [FX] - Metropolitan France [MX] - Mexico [FM] - Micronesia [MI] - Midway Islands [MD] - Moldova [MC] - Monaco [MN] - Mongolia [ME] - Montenegro [MS] - Montserrat [MA] - Morocco [MZ] - Mozambique [MM] - Myanmar [Burma] [NA] - Namibia [NR] - Nauru [NP] - Nepal [NL] - Netherlands [AN] - Netherlands Antilles [NT] - Neutral Zone [NC] - New Caledonia

[NZ] - New Zealand [NI] - Nicaragua [NE] - Niger [NG] - Nigeria [NU] - Niue [NF] - Norfolk Island [KP] - North Korea [VD] - North Vietnam [MP] - Northern Mariana Islands [NO] - Norway [OM] - Oman [PC] - Pacific Islands Trust Territory [PK] - Pakistan [PW] - Palau [PS] - Palestinian Territories [PA] - Panama [PZ] - Panama Canal Zone [PG] - Papua New Guinea [PY] - Paraguay [YD] - Peoples Democratic Republic of Yemen [PE] - Peru [PH] - Philippines [PN] - Pitcairn Islands [PL] - Poland [PT] - Portugal [PR] - Puerto Rico [QA] - Qatar [RO] - Romania [RU] - Russia [RW] - Rwanda [SH] - Saint Helena [KN] - Saint Kitts and Nevis [LC] - Saint Lucia [MF] - Saint Martin [PM] - Saint Pierre and Miquelon [VC] - Saint Vincent and the Grenadines



[WS] - Samoa	[SZ] - Swaziland
[SM] - San Marino	[SE] - Sweden
[SA] - Saudi Arabia	[CH] - Switzerland
[SN] - Senegal	[SY] - Syria
[RS] - Serbia	[TW] - Taiwan
[CS] - Serbia and Montenegro	[TJ] - Tajikistan
[SC] - Seychelles	[TZ] - Tanzania
[SL] - Sierra Leone	[TH] - Thailand
[SG] - Singapore	[TL] - Timor-Leste
[SK] - Slovakia	[TG] - Togo
[SI] - Slovenia	[TK] - Tokelau
[SB] - Solomon Islands	[TO] - Tonga
[SO] - Somalia	[TT] - Trinidad and Tobago
[ZA] - South Africa	[TN] - Tunisia
[GS] - South Georgia and the	[TR] - Turkey
South Sandwich Islands	[TM] - Turkmenistan
[KR] - South Korea	[TC] - Turks and Caicos
[ES] - Spain	Islands
[LK] - Sri Lanka	[TV] - Tuvalu
[SD] - Sudan	[UM] - U.S. Minor Outlying
[SR] - Suriname	Islands
[SJ] - Svalbard and Jan Mayen	

[PU] - U.S. Miscellaneous Pacific Islands [VI] - U.S. Virgin Islands [UG] - Uganda [UA] - Ukraine [SU] - Union of Soviet Socialist Republics [AE] - United Arab Emirates [GB] - United Kingdom [US] - United States [UY] - Uruguay [UZ] - Uzbekistan [VU] - Vanuatu [VA] - Vatican City [VE] - Venezuela [VN] - Vietnam [WK] - Wake Island [WF] - Wallis and Futuna [EH] - Western Sahara [YE] - Yemen [ZM] - Zambia [ZW] - Zimbabwe

EDUCATIONAL GRANT TYPE

support_event - Support to Educational Events (inc. attendance) other_grant - Other Educational Grants (Fellowships, Schollarships...)