

study PORTAL

ADMIN :H3 A Dashboard Overview (+) Patier 0 Tot o 2,345 3,568 1.6k 1.4% 1.28 :Healthentia COQU θ I committee the 327 ~ (1: (1,132 total que C 06:25:00 @ 100 12

INVESTIGATOR MANUAL

APRIL 2020

HEALTHENTIA v2

CE



Innovation Sprint SprI Clos Chapelle-aux-Champs 30 Bte 1.30.30 1200 Brussels, Belgium

v2 (27/04/2020)

HEALTHENTIA is a medical decision support software developed by INNOVATION SPRINT and intended monitor, detect, offer virtual coaching services and generate automatic alerts regarding events, based on Real World Data gathered from patient taking part of clinical investigation, or those using it as a medical or wellbeing device.

The intended use of the device is: Software intended for monitoring of non-vital parameters to support decision making and virtual coaching of patients during clinical trials or under a medical or wellbeing treatment context.



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DOCUMENT HISTORY

version	Date	Author	Description				
0.1	6/12/2018	Konstantina Kostopoulou	ТоС				
1.0	14/3/2019	Konstantina Kostopoulou	Healthentia version 1				
1.1	14/5/2019	Konstantina Kostopoulou	Healthentia version 1 -upd				
2.0	27/4/2020	Sofoklis Kyriazakos	Healthentia version 2				



1 GETTING STARTED

HEALTHENTIA can be used both by individuals and by sponsors of clinical trials. Individuals can report and monitor their outcomes (e.g. symptoms) and activity and receive automatic-generated questionnaires for wellbeing. Aggregated data provided after users' consent, can be processed for conducting non-profit research studies. Clinical trial sponsors can operate HEALTHENTIA to collect ePROM/ePREMs under the appropriate regulatory framework (e.g. Good Clinical Practice) to carry out study protocols, often by the use of a PaaS instance of the platform. Individuals, depending on their consent information, may receive invitation to participate in research studies.

This manual is targeting Organization Admins, Study Admin, Investigators and other authorized personnel of the Study Portal.

1.1 LOGIN/REGISTER AS A PORTAL USER

To login user should go to the login page, which is available in <u>https://saas.healthentia.com</u> for the SaaS version, or a specified URL for the PaaS version.



Users receive an invitation from an Organization Admin to register their account and enter in the portal in the allocated study with an allocated role.



2 STUDY MANAGEMENT

2.1 STUDY OVERVIEW

After log in you are directed to the Study Overview Page – My Studies, which has a list of your available studies and some overall statistics. You can access your Studies, edit them or create a new one.

Healthentia Real World Outcomes	MY STUDIES			🖈 🧟 📧 Innovation Sprint
symptom Tracker 🗸 🗸 🗸 🗸				
A DASHBOARD	·			
SUBJECTS ~	Overall	Tracked Activity	Adherence	Last week's activity
L USERS Y	18 studies	95218 days	6172 events from 376 participants	6 subjects with reported events
🚺 ALERTS 🗸 🗸	rs 785 participants		15216/16141 answered questionnaires	1 participants
C ECONSENT				
🚰 MESSAGES 😽 🌖 🗸				
	Show: 10 🗸			Create Study
QUESTIONNAIRES ~			Betlente	
ず system 🗸 🗸	Icon ^ Name	Organization 0 Codename 0	Disease \bigcirc Patients \bigcirc Status No	Alerts C Actions
🗩 devices 🗸 🗸	Search Names	e.g. Healthent e.g. HEAL	Search Diseases Search Patie Select	✓ # of Alerts
audit trail. 🗸 🗸				
	Monoclonal Antibodies	ORG_1 MoAbs	Remote Covid19 Therapy 0 Oncome	0 🗹 I 🖕 I 🧰
	Virtual Ward	ORG_1 VIRTUALWAR	Ovarian Cancer 3 ONGOING	9 🕑 i 🔤 i 💼
	VITO Demo Study	ORG_18 VITO_Demo	Observational 7 ONGCING	0 🕑 i 🖕 i 🗇
	W Digital Check-up	ORG_17 DIG CHECK	Health Assessment 9 ONCOMO	9 🕑 i 🚘 i 💼
Version: 2.9.3 (210513) © 2021	IPF Vaccine Study	ORG_6 IPFVaccine	IPF 69 ONGOING	👓 🗹 i 📷 i 🛅
	🍟 iHelp	ORG_16 iHelp	Pancreatic Cancer 3 ONGCING	0 🕑 i 🔤 i 🛅
	🥏 Beia	ORG_12 BEIA	4 сласона	S 🛛 🖉 i 🔤 i 🤠
	E KEYRUS Demo	ORG_11 Keyrus		📵 🕑 i 🎽 i 💼 i 💼
	IMEC Demo	ORG_10 imec	Health Monitoring 1 (ONCONING)	8 🛛 🖉 l 🔤 l 🛅
	Med-ex Demo	ORG_9 Med-ex	Physical Activity Monitoring 1 (ONGOING)	0 🗹 l 🔤 l 🏛
	Showing 1 to 10 of 18 entries			⊢ 1 2 →



2.2 SETTING UP A NEW STUDY

From this first page, you have the option to create a new study. Depending on the type of study, investigator provides different information. In Figure 4 one can see the available configurations for the study per se but also the mobile App. There is a selection of available widgets to select for the new study and configure the data sources but also several fields to fill in like Name, Code, logo, Languages, therapeutic area, duration and consents.

Healthentia Study Portal

Healthentia Real World Outcon	nes	CREATE STUDY							- 10	KK Konstantina	
Symptom Tracker	~										
A DASHBOARD		GENERAL									
	~	Account Settings									
L USERS	~	Name: *		Therapeutic Area:		Codename: *					
e alerts	~										
CONSENT	~	Protocol:		Duration In Months	s:		Start Date:	End D	ate:		
A MESSAGES	••						2021/05/14				
	~	Primary Language: *	Add More Langua	ges:				Study Logo: 👔			
	~	Select	*								
SYSTEM	~										
🖉 DEVICES	~							Choose File No file chose	en		
AUDIT TRAIL	~	Additional Services									
		Video-Chat	Multicenter		Interactive Map						
		MOBILE CONFIGURATION									
		Study Information Page:					Study Logo on App: 🚯				
		Leave empty for no information Page					Choose File No file chosen				
		Pop-up for Study's terms & Privo	acy 😗								
		Pop-up for Study's terms & Prive Short Term's Description:	acy 🕣				Terms of Use URL: 1				
							Terms of Use URL: ①				
		Short Term's Description:									
		Short Term's Description:				6	Leave empty for no Terms of Use				
		Short Term's Description:				ŀ	Leave empty for no Terms of Use Privacy Policy URL:				
		Short Term's Description:	escription	Allowing Reporting		Contact	Leave empty for no Terms of Use Privacy Policy URL:				
		Short Term's Description: Leave empty for no Short Terms D Available Consents C General Terms	escription	Allowing Reporting		Contact	Leave empty for no Terms of Use Privacy Policy URL: Leave empty for no Privacy Policy				
		Short Term's Description: Leave empty for no Short Terms D Available Consents C General Terms Additional App Widgets	escription		Uquid consumpt		Leave empty for no Terms of Use Privacy Policy URL: Leave empty for no Privacy Policy ad by doctor in case of need				
		Short Term's Description: Leave empty for no Short Terms D Available Consents Ceneral Terms Additional App Widgets Treatment Reminder	escription		Liquid consumpt		Leave empty for no Terms of Use Privacy Policy URL: Leave empty for no Privacy Policy				
		Short Term's Description: Leave empty for no Short Terms D Available Consents C General Terms Additional App Widgets	escription		Liquid consumpt		Leave empty for no Terms of Use Privacy Policy URL: Leave empty for no Privacy Policy ad by doctor in case of need				
		Short Term's Description: Leave empty for no Short Terms D Available Consents Ceneral Terms Additional App Widgets Treatment Reminder	escription	uthentication	Uquid consumpt	ion	Leave empty for no Terms of Use Privacy Policy URL: Leave empty for no Privacy Policy ad by doctor in case of need				
		Short Term's Description: Leave empty for no Short Terms D Available Consents Oreneral Terms Additional App Widgets Treatment Reminder Activity Widget (Available Integ Fibit Sync	escription Two-Factor A rations) Ormin Sync	uthentication		ion	Leave empty for no Terms of Use Privacy Policy URL: Leave empty for no Privacy Policy ad by doctor in case of need Sleep Widget				
		Short Term's Description: Leave empty for no Short Terms D Available Consents C General Terms Additional App Widgets Treatment Reminder Activity Widget (Available Integ	escription Two-Factor A rations) Ormin Sync	uthentication		ion	Leave empty for no Terms of Use Privacy Policy URL: Leave empty for no Privacy Policy ad by doctor in case of need Sleep Widget				
		Short Term's Description: Leave empty for no Short Terms D Available Consents Oreneral Terms Additional App Widgets Treatment Reminder Activity Widget (Available Integ Fibit Sync	escription Two-Factor A rations) Ormin Sync	uthentication	Apple Health Syr	ion	Leave empty for no Terms of Use Privacy Policy URL: Leave empty for no Privacy Policy ad by doctor in case of need Sleep Widget	5ev	erity		
		Short Term's Description: Leave empty for no Short Terms D Available Consents C General Terms Additional App Widgets Treatment Reminder Activity Widget (Available Integ Fitbit Sync SUBJECT DETAIL PAGE CO	escription Two-Factor A rations) Ormin Sync	uthentication	Apple Health Syr	ion	Leave empty for no Terms of Use Privacy Policy URL: Leave empty for no Privacy Policy ad by doctor in case of need Seep Widget Android Sync	Sev	erity rapeutic Area		
		Short Term's Description: Leave empty for no Short Terms D Available Consents General Terms Additional App Widgets Treatment Reminder Activity Widget (Available Integ Fitbit Sync SUBJECT DETAIL PAGE COO First/Last Name	escription Two-Factor A rations) Ormin Sync	Fiscal Number	Apple Health Syr	ion	Leave empty for no Terms of Use Privacy Policy URL: Leave empty for no Privacy Policy ad by doctor in case of need Steep Widget Android Sync Study Dotes	Sev	erapeutic Area		
		Short Term's Description: Leave empty for no Short Terms D Available Consents General Terms Additional App Widgets Treatment Reminder Activity Widget (Available Integ Fitbit Sync SUBJECT DETAIL PAGE CO First/Last Name Managed Fitbit	escription Two-Factor A rations) Ormin Sync	titentication fiscal Number Tracker Description	Apple Health Syr	ion	Leave empty for no Terms of Use Privacy Policy URL: Leave empty for no Privacy Policy of by doctor in case of need Sleep Widget Android Sync Study Dates Mobile Description	Sev The	rapeutic Area tus		

Figure 4 - Create New Study



3 DASHBOARD

The user dashboard contains information of the selected study in tabs, e.g. Interactive map, Study Overview, Measured Activities Overview and Outcomes Overview. This is a customizable set of dashboard tabs; they depend on the Outcomes that each trial collects. The map is connected to a Location question, Measured activity requires a connection the mobile sensors (or fitbit, Garmin, etc) and the reported outcomes tab has a self-service mechanisms for questions asked in the questionnaire to be seen in two types of graphs

3.1 INTERACTIVE MAP

At the configuration of the study, the Study Admin can select to enable the interactive map if there are questions regarding location. Portal users can select parameters through several filters and have an overview of subject outcomes at a geographical level, as presented in Figure 5.

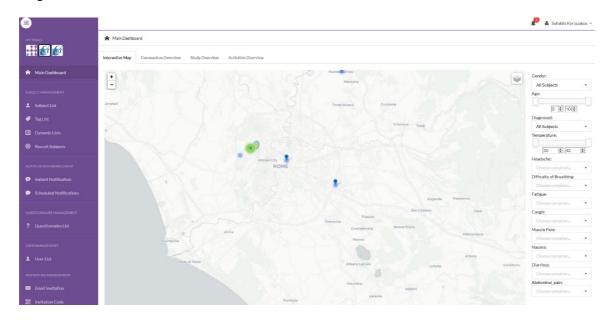


Figure 5: Interactive Map

3.2 BI

Further to the Interactive map, there are other tabs in the Dashboard that can be configured with study Overview statics, like registrations and protocol adherence – Figure 6.

Healthentia Study Portal



Figure 6: Study registration and compliance overview

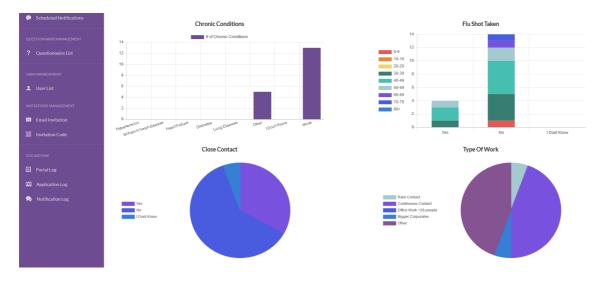


Figure 7: Study statistics overview



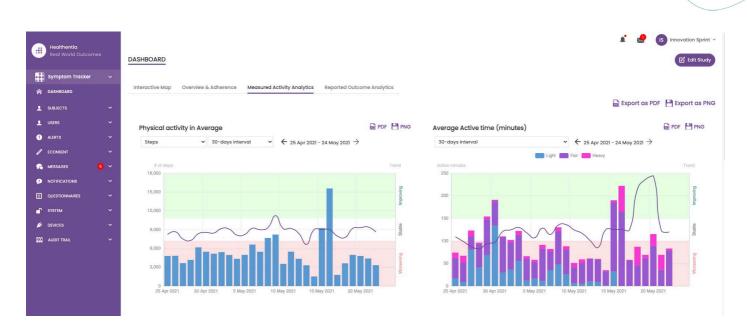


Figure 8: Measured Activity overview



4 SUBJECTS

4.1 ADD A SUBJECT

Subjects are either imported via an integration with an EDC into Healthentia as inactive subjects that are activated once they have logged in to Healthentia, they can be manually added by the button on the Subject List or invited through the system from the Subject Invitations. The email used for the invitation will be recognized by the system to allow them, at registration on the App to enter to the specific Study. **Not using the same email will not enroll the Subject in the correct Study.**

Healthentia Real World Outcomes	SUBJECT INVITATION		🖈 🔯 🚯 Innovation Sprint ~
💣 Interface 🗸 🗸			
😭 DASHBOARD			
	Show: 50 ¥		🖪 Invite Subject 🕹 CSV Invitations 🕹 Export
Subject List	Email © Invited On	Browser Time) - Role û Joined On (Browser Ti	me) 🗘 Invited By 🗘
Tag List Dynamic Lists	emal@healthentia.com		email@healthentia.com
Custom Fields	330d5182-7e49-4d6d-a7a4-81aac6a78e5a@healthentia.com 2021/05/03	16:15:48 Subject ⊘ 07/05/2021, 18:13:50	9f7l4f3f-0c02-4cbf-aa89-e7d75d83adc3@healthentia.com
Subject Invitations	flf524ee-cf6a-4321-adf3-4aadae35bf08@healthentia.com 2021/05/03	16:15:04 Subject ⊘ 11/05/2021, 17:03:03	9f7l4f3f-0c02-4cbf-aa89-e7d75d83adc3@healthentia.com
Codes	4fl2da93-2c3f-4a9e-9996-c28be8f83fbc@healthentia.com 2021/05/07	16:14:30 Subject ⊘ 07/05/2021, 16:27:41	9f7l4f3f-0c02-4cbf-aa89-e7d75d83adc3@healthentia.com
L USERS		L Invite Subject	
ALERTS ECONSENT Emai	:* Phone Number: (Required or	y for eConsent) Invitation Code:	
	ail +32 XXX XXXXXXX	No Code 🗸	A Send Email
SYSTEM			
Ď DEVICES ✓	1a095ecf-88f2-4c20-83fc-cea2eced6328@healthentia.com 2021/04/03	11:15:08 Subject 🔗 02/04/2021, 11:51:13	91714131-0c02-4cb1-aa89-e7d75d83adc3@healthentia.com
audit trail			
Healthentic from Innovation Sprint	3371209c-28a5-418b-ad0f-c1b24d5137e8@healthentia.com 2021/03/22	19:28:13 Subject ⊘ 22/03/2021, 19:33:29	9f7l4f3f-0c02-4cbf-aa89-e7d75d83adc3@healthentia.com

Figure 9 - Invite Subjects

Similarly, to the Email invitation above, the investigator can invite patients by providing them a code. Subjects can enter this code at the registration, even if they have not received an email. Once they register, they are automatically connected to that specific study only. They can be massively generated to use one per subject and or one can be used for all the subjects for the Study as seen in Figure 10

Healthentia Real World Outcome	əs								IS Innovation Sprint
<i>C</i> 1		INVITATION	I CODES				① Create Invit	ation Code 🔞 Gei	nerate Random Codes
f Interface	Ý								
A DASHBOARD									
	^	Show: 50	~						🕹 Export
Subject List		Active	Created On (Browser Time)	~ Code	Used Slots	0	Email Only	0 Document	0 Action
Tag List		~	14/01/2021, 12:44:42	Interface	0/50		YES	Unavailable	茴
Dynamic Lists		~	20/10/2020, 11:03:52	FUGN4N	0/1		NO	-	🕒 💼
Custom Fields		~	20/10/2020, 11:03:52	WMESEH	0/1		NO	-	🖄 🖨
Subject Invitations		×	20/10/2020, 11:02:09	VV/CDA7	0/2		NO	-	ß
Codes	~	Showing 1 to 4	4 of 4 entries	Senerc	🎇 Generate Invitation Code(s) 🛛 ×				- 1
. ALERTS	ř							Innovation Spr	int Spri v2 (21/03/2 aux-Champs 30
CONSENT	ř			Construction and			CE	Bte 1.30.30 1200 Brussels, I	
	ř			No. of Codes	Generetate				
QUESTIONNAIRES	ř								
SYSTEM	ř								
DEVICES	ř								
AUDIT TRAIL	~								

Figure 10 - Invitation Codes





In the Subject record, the portal user that has permissions to view or edit the patient details and view ePRO related data and measured activity can have access to the different tabs of information coming from different sources. They can even have the ability to complete questionnaires for them.

Healthentia Real World Outcom	nes	SUBJECT DETAILS					A.		IS Innovation	n Sprint ~
💕 Interface	~									
A DASHBOARD		Basic Details Reported Events	Questionnaires Notifications	Measured Activity Analytics	Consent Actio	ns				
	~							🕀 Log	g Event 👌	Export
L USERS	~	Show: 10 🗸								
. ALERTS	~	Event Title	\$ Status		0	Submitted On (Browser Time)				~
CONSENT	~	PHQ-9	Complet	ed	1	1/05/2021, 17:06:05				
	~	GAD-7	Complete	ed	1	1/05/2021, 17:05:16				
	~	EQ-5D-3L	Complet	ed	1	1/05/2021, 17:04:42				
SYSTEM	~	Showing 1 to 3 of 3 entries							-	1 -
🗩 DEVICES	~	-								

Figure 11 - Subject Details

4.3 SUBJECT LIST

The subject's list gathers in a table all patients assigned in the specific study. The list table gives an overview of important elements like dates, Questionnaire adherence, tags, activity status and more.

Healthentia Real World Outcome	əs	SUBJECT LIST							A 🛛 (IS Innovation Sprint ~
Interface DASHBOARD SUBJECTS		Filter by Tags	OVID19 POSITIVE DOSE 1 COVIDVAX	DOSE 2 COVIDVAX	FEEDBACK				NOT SYNCED	PAZIENTE FRAGILE
Subject List Tag List		Show: 50 V								🕹 Export
Dynamic Lists Custom Fleids Subject invitations		Sr.No	Email c eg: healthentia.com	Subject Id 🗘	Registration Date	Qrs Adherence Pending / Completed	Tags	Activity Source	Status O	Actions
		1	flf524ee-cf6a-4321-adf3- 4aadae35bf08@healthentia.com	15096001	11/05/2021	0/6	PSYCHOLOGICAL SUPPORT	NoTracker	ENROLLED	C 🖥 🛍
ALERTS		2	330d5182-7e49-4d6d-a7a4- 81aac6a78e5a@healthentia.com	19254317	07/05/2021	0/3	DOSE I COVIDVAX NOT SYNCED	Android	ENROLLED	🗹 🔒 🗇
		3	4f12da93-2c3f-4a9e-9996- c28be8f83fbc@healthentia.com	12296802	07/05/2021	0/7	PSYCHOLOGICAL SUPPORT NOT SYNCED	AppleHealth	ENROLLED	6 🖬 🗇
		4	9b37ed2a-3b49-444d-8a94- 6e26e7c8ddef@healthentia.com	24329179	07/05/2021	0 / 12	HIVSRQ SYMPTOM PSYCHATRIC SUPPORT NOT SYNCED FEEDBACK DOSE 1 COVIDVAX	AppleHealth	ENROLLED	🗹 🖬 茴
💉 DEVICES		5	0b0edlcb-c8ee-4568-85ee- dd729f69df33@healthentia.com dd1ed84d-20b3-4481-a743-	9524489	30/04/2021	0/7	FEEDBACK DOSE I COVIDVAX	AppleHealth	ENROLLED	🗹 🖬 🗇
Healthentia from Innovation Sprin	int	6	dd1ed84d-20b3-4481-a743- bda58102c22d@healthentia.com	12718649	17/04/2021	1/0		NoTracker	ENROLLED	🗹 🖥 🗇

Figure 12 Subject list

4.4 TAGS & DYNAMIC ALERTS





entry in the system or depending on their answers in the questionnaires. These tags can be than attached to an Alert seen in Figure 14. All Alerts are featured in a table as seen in Figure 15. As in all sections of the portal all data are exportable to an excel file.

Home / Tag					⊕ Add Ta
Show: 10 ¢					Export data to exc
Title	 Created On 	٥	Status	\$	Actions
e.g. Chronic	Created On	Ē	-Select-	٠	QIN
Acute	10/09/2018		INACTIVE		1
Chronic	08/09/2018		INACTIVE		🗹 । 💼
Congenital	13/10/2018		ACTIVE		🗹 । 🏛
Diagnosed	08/09/2018		ACTIVE		🗹 I 💼
language - DE	22/10/2018		ACTIVE		🗹 l 💼
language - EN	22/10/2018		ACTIVE		C 1 💼
Vertigo	15/11/2018		ACTIVE		🗹 I 💼

Figure 13 Tags List

CREATE DYNAMIC ALERT

Name: *	Status:	
	Active	~
Portal Alert Message: (You can use (Shortia) to incluse receipient's Short id in your message)		
Push Notification Message:		
Email List. (Enter emails separated by spaces or commas)		
Email Message: (You can use {Shortia} to incluse receipient's Short id in your message)		
API Endpoint to Call:	API Alert Codename:	
Tags to Apply:		

Figure 14 - Create New Alert

Cancel 😣 🍸 Create 🕣

Healthentia Real World Outcomes		DYNAMIC ALERT						A (KK K	_	tina Kostopoulou ~ dd Dynamic Alert
👩 Interface											
A DASHBOARD											
		Show: 10 🗸									🕹 Export
L USERS		Title	^	Web Alert 🗘	Push Alert 🗘	Email Alert 🗘	API Call	Apply Tag 🗘	Status	0	Actions
I ALERTS		COVID-19 POSITIVE		~	×	×	×	•	ACTIVE		図1曲
Dynamic Alerts/Tags									_		
CONSENT		DOSE 1 COVIDvax		×	×	×	×	*	ACTIVE		🗹 🗇
		DOSE 2 COVIDvax		×	×	×	×	×	ACTIVE		🗹 l 🧰
		FEEDBACK		~	×	×	×	×	ACTIVE		🗹 I 💼
SYSTEM		Frailty Alert		~	×	×	×	×	ACTIVE		🗹 l 🗇
DEVICES		HIGH COVID risk		~	~	×	×	×	ACTIVE		🗹 💼
001 AUDIT TRAIL		HIVSRQ symptom		~	×	×	×	¥	ACTIVE		🗹 💼
		Low Adherence		×	~	×	×	~	ACTIVE		🗹 💼
		LOW COVID risk		×	~	×	×	~	ACTIVE		🕑 💼
		Psychiatric support		×	×	×	×	~	ACTIVE		🕑 💼
Healthentia from Innovation Sprint		Showing I to 10 of II entries								+	1 2 →

Figure 15 - Dynamic Alerts List

4.5 ALERTS DASHBOARD

The Alerts are shown in a separate Dashboard where the portal user has an overview of what tags are allocated and whether a patients requires an immediate action or has low adherence in his reporting of questionnaires.

Healthentia Real World Outcom	nes	ALERTS			, k	🔀 🥂 Konstantina Kostopoulou 🗸
f Interface						
A DASHBOARD		Filter by Tags (COVID19 POSITIVE		DOSE 2 COVIDVAX FEEDBACK FITBIT TOKEN EXPIRED		YMPTOM LOW ADHERENCE
		Filter by Tags COVID19 POSITIVE LOW COVID RISK NOT SYNCED		SYCHIATRIC SUPPORT PSYCHOLOGICAL SUPPORT		LOW ADHERENCE
L USERS						
e alerts		Show: 50 🗸				
CONSENT		Triggered On (Browser Time)	✓ Subject Id 0	Alert Message	Тад	Manager ^
		21/04/2021, 14:21:27	20575866	Patient 20575866 needs psychological support	PSYCHOLOGICAL SUPPORT	🧭 Giulia Micheli
	~ ~	20/04/2021, 16:30:02	14455901	Subject 14455901 has «Questionario sulla Salute - EQ- 5D-3L» as pending		🖉 Giulia Micheli
SYSTEM	, ,	18/04/2021, 16:30:01	04588190	Subject 04588190 has «Questionario sulla Salute - EQ- 5D-3L» as pending		🖉 Giulia Micheli
audit trail		18/04/2021, 13:15:19	14455901	Patient 14455901 is identified as FRAIL	PAZIENTE FRAGILE	🖉 Giulia Micheli
		18/04/2021, 13:12:09	14455901	Subject 14455901 has an HIVSRQ symptom alert	HIVSRQ SYMPTOM	🧭 Giulia Micheli
		17/04/2021, 19:19:56	03806999	Patient 03806999 needs psychological support	PSYCHOLOGICAL SUPPORT	🔗 Giulia Micheli
		17/04/2021, 16:30:02	03806999	Subject 03806999 has «Questionario sulla Salute - EQ- 5D-3L» as pending		Subject answered the questionnaire.
		15/04/2021, 16:30:01	15929649	Subject 15929649 has «Questionario sulla Salute - EQ- 5D-3L» as pending		🖉 Giulia Micheli
Healthentia from Innovation Sp	erint	10/04/2021, 09:10:41	11294295	Patient 11294295 needs psychological support	PSYCHOLOGICAL SUPPORT	🖉 Cristina Seguiti

Figure 16 - Alerts Dashboard





The Dynamic lists are used to group patients in a dynamic way. We create grouping requirements and patients are added automatically in a list when they meet the criteria. The attributes of patients that can be used as criteria for filtering the patient list are status, screening, termination or treatment switch date and even using tags that are explained below. As in all sections of the portal all data are exportable to an excel file, as presented in Figure 17.

DYNAMIC LIST	TS										€ Add Dynamic List
Show: 10 🔹	×										🕹 Export
Sr.No	Title ^	Description	0	Created On			0	Status		0	Actions
	e.g. Subjects	e.g. Description		Created On			i	Select		~	
1	test			05/03/2021				ACTIVE			🗹 🛅
Showing 1 to 1 of 1	i entries	Figure 17	Dyna	mic List table							- ♥ →
	II Dynamic List Detail (Edit Mode)										1
	😭 Home / Dynamic List / Edit										
	Query Title: *			Status:							1
	Diabetic Patient Group			Inactive						\$	
	Query Description: This is a list with patient with Diabetes										
	Query Criteria Patient Attributes * Status:	Gender:	s	Screening Date:			Study Complet	ion Date:		h	
	Active	Female	•	02/12/2018	0		12/12/2019		۲	Ē	
	Weight(kg):	Height(cm):			Day	of treatm	ent switch:				
	65,00	1,85			20	/02/201	9		0	Ē	
	Treatment A:		1	Treatment B:							
	A.			В							
	Filter Patient By Tags: Diagnosed ×										
								Cancel	8	Save 🏵	

Figure 18 - Dynamic list details



5 NOTIFICATIONS

5.1 NOTIFICATION LOG

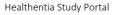
In the section of Notifications, we can see all communication sent by the system to patients, we can create instant notifications or scheduled. All notifications are listed by date in the Notification List and you have an overlook of the content of these notifications and if their type. As in all sections of the portal all data are exportable to an excel file, as presented in Figure 19.

Healthentia Real World Outcomes	NOTIFICATION LOG			A 🖾	KK Konstantina Kostopoulou 👻
Symptom Tracker 🗸 🗸					
A DASHBOARD					
L SUBJECTS V	show: 10 🗸			4 B	port 🛛 Clear Search Filters
👤 USERS 🗸	Description 0	Туре 🗘	Content Recipients	Sent On (User Time) 0	Sent On (Your Time) 🗸 🗸 🗸 🗸 🗸
🤚 ALERTS 🗸 🗸	e.g. Monthly Reminder	Select 🗸		24/05/2021	24/05/2021
/ ECONSENT Y	e.g. working Kerninder	20lact 🔹			
nessages 🧴 🖊 🗸	Treatment Reminder	Treatment Reminder	View Content	24/05/2021, 14:24:09	24/05/2021, 15:24:09
	Severity Alert	Severity Alert	E View Content	24/05/2021, 13:05:33	24/05/2021, 14:05:33
Instant Notification					
Scheduled Notifications	Treatment Reminder	Treatment Reminder	View Content	24/05/2021, 09:30:07	24/05/2021, 10:30:07
Notification Log	Treatment Reminder	Treatment Reminder	View Content (1)	24/05/2021, 09:00:01	24/05/2021, 10:00:01
 QUESTIONNAIRES SYSTEM 	Treatment Reminder	Treatment Reminder	Uiew Content	24/05/2021, 08:01:05	24/05/2021, 09:01:05
DEVICES Y	Treatment Reminder	Treatment Reminder	View Content	23/05/2021, 21:30:14	23/05/2021, 22:30:14
	Treatment Reminder	Treatment Reminder	Tiew Content	23/05/2021, 09:30:06	23/05/2021, 10:30:06
	Treatment Reminder	Treatment Reminder	E View Content	23/05/2021, 09:00:15	23/05/2021, 10:00:15
	Treatment Reminder	Treatment Reminder	🖹 View Content	23/05/2021, 08:01:29	23/05/2021, 09:01:29
	Treatment Reminder	Treatment Reminder	Tiew Content	22/05/2021, 21:30:12	22/05/2021, 22:30:12
	Showing 1 to 10 of 6,261 entries			- 1	2 3 4 5 627 →



5.2 INSTANT NOTIFICATIONS

Instant Notifications are the ad hoc messages that the investigator can send to a patient that hold a simple message or accompany a questionnaire. You can select individual recipients for the notification from the full subject list or filter by using tags or Dynamic Lists as seen in Figure 20.



Healthentia Real World Outcome	IS .	INSTANT NOTIFICATION			A 📾	KK Konstantina Kostopoulou 👻
Symptom Tracker	~					
A DASHBOARD		Notification Title: *				
	~					
L USERS	~					h
. ALERTS	~	Select Questionnaire:				
CONSENT	~	Abdominal pain				*
😪 MESSAGES	• •	Choose direct recipient: *				
	^	FR106 ×				
Instant Notification		Choose Tags: *		Select Existing Dynamic List: *		
Scheduled Notificatio	ins			Select Dynamic List		v
Notification Log						Search Q
	~					
🗗 System	~					
🗩 DEVICES	~	No	Subject ID	Registration Date		
	~	Ĩ	FR106	25-Apr-2020		
Hadnes to from provation fight						Cancel 😣 Send 🔿

Figure 20 - Instant Notification

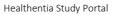
5.3 SCHEDULED NOTIFICATIONS

Scheduled notifications are the ones that are created in the beginning of the study and are used to schedule the questionnaires to be sent to a group of recipients based on a filtering by tags or dynamic lists or to the whole list.

The scheduling of a notification can be done based on a regular Date with a Daily, weekly or Monthly interval sent once at a specific time or recurring. The system also allows the coordinator to send notifications based on the protocol's specific dates and X days before or after these days. You can see the Notifications List at Figure 21 and the New Scheduling Notification at Figure 21

Healthentia				📫 🖂 🧰 Kon	stantina Kostopoulou 🗸
Healthentia Real World Outcomes	SCHEDULED NOTIFICATION			⊕ Add 9	icheduled Notification
Symptom Tracker 🗸 🗸 🗸 🗸					
A DASHBOARD					
👤 SUBJECTS 🗸 🗸	Show: 10 🗸			🕹 Export 🛛 🗙	Clear Search Filters
L USERS Y	Description	Туре	Content	Status 0	Actions
. Alerts		1160	, where		
<pre> econsent </pre>	e.g. Monthly Reminder	Select	~	Select - 🗸	
😪 messages 🛛 🕚 🗸	VAS FOR PAIN	Daily (Baseline Date)	E View Content	ACTIVE	🗹 I 💼
	Weekly COVIDI9 Self-Assessment	Weekly	View Content	INACTIVE	1
Instant Notification					
Scheduled Notifications	Showing 1 to 2 of 2 entries				





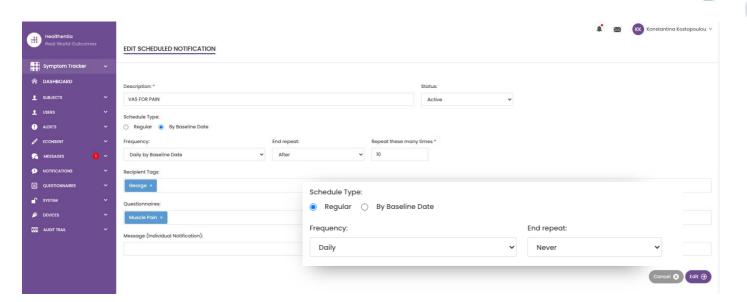


Figure 22 - New Scheduled Notification





6 MESSAGES-TELECONSULTATION

6.1 MESSAGE INBOX

End-users of the mobile app if the feature is enabled they can send a Message to the Investigator/study assistant and start a conversation. If needed the investigator can start a teleconsultation video link that will be valid for 15 minutes. See inbox in Figure 23 and the conversation in

Figure 24.

				Æ	×	KK Kon	stantina Ko	ostopoulou ~
UNANSWERED CONVERSATION LIST								
show: 10 🗸								🕹 Export
Subject \bigcirc Title	0	Last Message	0	Sent On		~ Cate	gory 0	Reply
S8CYT Information		Subject: Like arm pain		04/05/2021, 18:20:28		HEAL	н	5
showing I to I of I entries							-	

Figure 23 - Message Inbox





hello 12:54 PM	
Teleconsultation	
Teleconsultation request was sent.	
12:55 PM	
eleconsultation has been completed. 12:57 PM	
Teleconsultation	
Teleconsultation request was sent.	
12:68 PM	
eleconsultation has been completed. 12:58 PM	
Teleconsultation	
Teleconsultation request was sent.	
6:37 PM	
eleconsultation has been completed.	КК

Figure 24 - Message conversation

6.2 TELECONSULTATION

If needed, the investigator can start a teleconsultation video link that will be valid for 15 minutes, as shown in the Figure below.

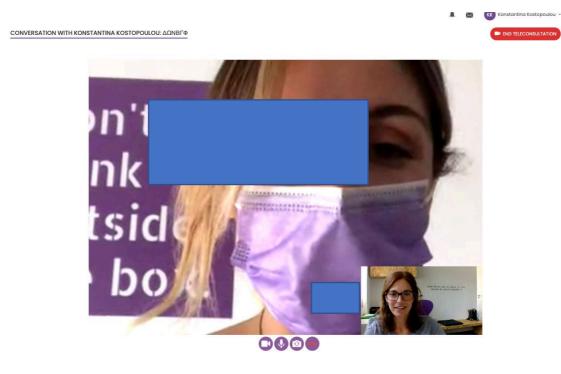


Figure 25 – Teleconsultation



7 ECONSENT

7.1 ECONSENT

If the trial has an active eConsent, the eConsent is triggered by the Healthentia app after the user has registered and agreed with the Terms of the Healthentia application. Each eConsent form must have a unique Version and a unique Title in the context of this study or site (in case of multicenter trials). When creating or editing an eConsent form, users with the appropriate permission shall be able to: (1) add a plain text field to write the "Terms" of the eConsent Form; (2) add a plain text field to write the "Introduction" of the eConsent form; (3) upload a url from a video streaming provider to the eConsent form; and (4) define a Status. An eConsent setup has three status: "draft", "active" and "inactive". While in "draft" mode, the eConsent is editable. Once the investigator changes its status to "active", the eConsent is locked and no longer editable. The "inactive" status is given to eConsent forms that are no longer active but that have been signed at least by one study participant. See Figure 26 and Figure 27.

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10
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Figure 26 - eConsent list

	Stotus Venior.*		
#			
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Hit symptom lidzeer			
Contributed	Content Tisti *		
H Callborry	Text		
🗐 Deep Phenotyping	indo: *		
	Normal + B Z U B A # 1E HE IN GO 9		
🛓 лациот макалинит 🗸 🗸			
🖉 соснарят минисирал	These changed the description after editing		
P CONSINT WARMANN			
🕖 нотволлов минисонол 🗸 🗸			
-			
🖬 самоника нескология — м			
LE LETTERANDOMINE Y			
MATATIONS NAMED AND THE Y			
	Consert Terms:		
			h.
	Viduo		
	Serrary		
	https://distribution/sicconductions/paracelsis-stati-com-attended/in/ms/advisionant/20/consulption/ms/s		
	Comprehension		
	Include Comprehension Questionnaire:	Score threshold to proceed to signings	
	compreh 👻	10	
	Signing		
	Cruci Verification SPhone Verili cation		
			Concel 🕲 Sove 🛞
He show do leave to warefore Sprint			Concel 🕲 📘 Sorve 🛞



The process of signing an eConsent form can only be completed after a mobile app user has verified his identity providing a code received via email or mobile phone. Once the participant has signed the eConsent, a pdf document is created with the name, date and signature of the participant on top of the Terms plain text. The pdf document created after the participant signed the eConsent is saved in the Healthentia Patient documents with type "consent". Once the participant has signed the eConsent, the tag of the eConsent in the subject list changes from "not started" to "requires signature".

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tanthood.									
mod spannshing	Show: 50 ¥								d Escel
сполтинионог н	Sella C	Email	Subjectio 2	Consent Info :	Version	I Consent Date	C Comprehension	Stotus :	Ele I
sungeet Uat Tog Uat		eg:bestterda.com/ 5	aparia B				8	··· Select ··· · · ·	
	1	00077567-5470-4993-6655- 0564 (st08) sogt herd her tis com	34749		0			-	4
Recruit Subjects	229	nose nos - sense and - conservation - Orbol 4-4 (Doecog) Availater to com	45049	HIND 2011		16/1/2020		commune	1
eConsent Setup	2	0200754w c4c2 4777 0d24 toropedatographicational con-	90134		0			-	4
Patient Status	1	0525-0662-6930-4060-firs3e- Oed120062651g=teotherste.com	XMEY	GHEDTELL - PARCELVEC -	0			-	ů.
нотичален назыскант — —	4	02280ees-fait-4c60-5ee0- 012252ec507eg/read/works.com	CREAM	(1000101 - FARCELAND)	0			-	3
даннынан англилт	6	05x0cr0x-03x1-47/6-5044- notam99ex32.cgm.coltheadis.com	N86451	(100.000 (100.000.)	0			(1999)	4
umussonun v	5	teos calass-bet i-com-al/s 2eb2553445-c3g/wei trant b.com	TPSCS	(DECUTING - ANECHANIC)	0				4
MUTTOR MANAGE	<u>8</u> :	07336386 bbcb 4560 be2s Doubthat9989899Mentity Froom	197.964		0			(1111)	4
	8	08/750306-108-4855-3851H Sid12c975c5digdreeithewils.com	27//CD	GHCDTER - FRACELORC -	0			-	4
		09714003-66355-4776-6155- 400505556657@Rev Inanfoxoom	NWS.	ORCHER - SNEELVEL	0				4
	1	09d5ec65-120e 4560-002 GEORETHINGSECIENT PRESSOR	98977		0			-	4
	10 K	Homoston-kannektivt-ninke Stobe-0272764 git sobberde com	V50//51	GROUPS - PARCELVEC.	0			(1000)	÷
	u.	0d070012_c0.cc_428_c521- 095001e3557283Moo Brankasoon	(13-90)	(0			-	4
	15	00000002-0011-4930-6972-	04549		0				4

Figure 28 - eConsent PDF list

8 QUESTIONNAIRES

8.1 QUESTIONNAIRE LIST

The portal allows the study coordinators to create a questionnaire with different question types but also allows the questionnaire to be uploaded from a specified excel file. These questionnaires are then sent to the patient through a notification. In the Questionnaire management one can see the list of available questionnaires in the study and the number of questions that each has as well as their status and date created. As in all sections of the portal all questionnaires can be exportable to an excel file.

Healthentia Study Portal

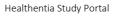
Healthentia Real World Outcomes	QUESTIONNAIRE MANAGEMENT					Add Questionnaire		Innovation Sprint ~
Symptom Tracker 🗸 🗸								
A DASHBOARD								
👤 SUBJECTS 🗸 🗸	Show: 50 ¥							🕹 Export
USERS ~	Title	^ Codename	≎ Kind ≎	No. of Questions	Types	Created On	Status 🗘	Actions
MESSAGES U ~	e.g. Diabetic Questionnaire	e.g. Q_MUSCLES	Selec 👻	e.g.11	e.g. Initial	02/10,	Seleci 🗸	QIX
	Abdominal pain	ISPRINT_ABDPAIN	Simple	1	ADD-EVENT-LIST	26/03/2020	ACTIVE	🗹 I 🗇
Questionnaire List	Add or take photo		Simple	1	ADD-EVENT-LIST	24/04/2020	ACTIVE	🗹 l 💼
audit trail 🗸 🗸	Body temperature	ISPRINT_FEVER	Simple	1	ADD-EVENT-LIST	18/03/2020	ACTIVE	🗹 🗇
	Cough	ISPRINT_COUGH	Simple	2	ADD-EVENT-LIST	18/03/2020	ACTIVE	区 曲
	Diarrhea	ISPRINT_DIARRHEA	Simple	1	ADD-EVENT-LIST	26/03/2020	ACTIVE	区 世
	Difficulty of breathing	ISPRINT_DBREATH	Simple	1	ADD-EVENT-LIST	26/03/2020	ACTIVE	🗹 🗇
	eConsent comprehension Assessment	econsent	Simple	2	ECONSENT QUESTIONNAIRE	16/02/2021	ACTIVE	🗹 I 🗇
	Emotional State		Simple	1	ADD-EVENT-UST	06/05/2020	ACTIVE	区 曲
	Fatigue	ISPRINT_FATIGUE	Simple	1	ADD-EVENT-LIST	18/03/2020	ACTIVE	区 世
	Headache	ISPRINT_HEADACHE	Simple	1	ADD-EVENT-LIST	26/03/2020	ACTIVE	🗹 🗇
	Initial Questionnaire	ISPRINT_COVID19	Simple	n	INITIAL	16/03/2020	ACTIVE	🗹 l 🛅

Figure 29 Questionnaire Management

When creating a new one you define the title and questionnaire type (select from a list created by the admin) and upload a characteristic image for it if you want it to be shown on the app and start adding the questions one by one. In the question options you can choose from a variety of UI controls like if the question is a single, multiple, entry text or slider bar as presented in Figure 30.

Healthentia Real World Outcomes					🕻 🖂 🚺 Irida Manika 🗸
	VIEW QUESTIONNAIRE				
Symptom Tracker 🗸 🗸					
A DASHBOARD	Title (EN):	Title (II):		Codename:	
👤 SUBJECTS 🗸 🗸	test			test	
👤 USERS 🗸 🗸	Types:			Status:	
🕚 ALERTS 🗸 🗸	Types.			Active	~
👧 messages 🛛 🗸					
NOTIFICATIONS ~	Upload Image: Color: 6e4c91	Description:			
QUESTIONNAIRES ¥	Image: Second				
audit trail 🗸 🗸					
					li
	Choose File No file chosen				
	QUESTION LIST				Add Question
					Reset Sorting/Routing
	No Code Question		UI Control	Routing	Actions
	1 COUGH Do you have a cough?		Single Choice	Options Routing	1 🖸 🖻
	2 COUGH_TYPE Define your cough type:		Single Choice	Options Routing	20
Healthentia from Innovation Sprint					Cancel 😣 Save 🏵

Figure 30 - Simple Questionnaire Details



Real World Outcomes	VIEW COMPOSITE QUESTIONNAIRE	
🕈 Interface 🗸 🗸		
DASHBOARD	۲.: (<u>۱۱)</u> • •	Codename:
SUBJECTS Y	HIVSRQ Part 2 (composite)	HIVSRQCOMP_P2
USERS Y	Types:	Status:
ALERTS ~		Active
econsent ~	Upload Image: Color: * Description:	
NOTIFICATIONS ~	4AB522	
QUESTIONNAIRES Y		
system 🛩		
DEVICES Y	Remove	
	QUESTIONNAIRE ROUTING • Send Questionnaire: y #XXX #XXXX 35av >=v 1 ADD Ø 38av >=v • THER: Send Questionnaire: • Send Questionnaire: V • Send Questionnaire: v • Send Questionnaire: v • Send Questionnaire: v	
	Send Questionnaire: ADERENZACOMP Ind Questionnaire	
	ELSE: New Condition: IF All the following conditions are met: 35a v >= v 1 AND Assa check	
	THEN: Send Questionnaire: V PHQ-9COMP V Continue: V	
	Send Questionnaire: ADERENZACOMP Ind Questionnaire	
	ELSE: New Condition: IF All the following conditions are met:	
	$35a \vee$ (\vee 1 AND ($36a \vee$)= \vee 1 ($34d$ Check	
	THEN: Send Questionnaire: GAD-7COMP Continue:	
	Send Questionnaire: ADERENZACOMP End Questionnaire V	
	ELSE: Send Questionnaire: ADERENZACOMP End Questionnaire	

Figure 31 - Composite Questionnaire



9 USERS

9.1 ROLES & PERMISSIONS

This section is used by the admin to create the main roles and their permissions in the portal sections. Permissions can be configured for viewing, editing and delete, as depicted in Figure 32.

Roles & Permissions					
ome / Roles & Permissions			Role / Roles & Permissions / Create		
		Name: *			
	👔 Export data to excel	Role Access Permissions:	All		
<u>^</u>	Actions		A Destient Greate Gett		
	QIX		📄 💭 Details 🔺 🔝 🛺 Object		
	🗹 I 🧰		iii 🧾 Create iii 🔐 Edit iiii 🤐 Delete		
	C 1 💼		🔝 🥥 Details 💷 🥥 Instant Notification 🔺 🥅 🚇 Notification Template		
	see 1		Create Grade		
	^	Actions Q I ⊠ C I ₪ C I ₪ C I ₪	Actions Actions Actions Control to the Access Permission: Role Access Permission: Control to the Access Permission: Control to the Access Permission: Control to the Access Permission:		

Figure 32 Role Management and Add new Role

9.2 USER LIST

In the users list you can find all the portal users that are assigned in the study. The study admin can create or invite new users or assign existing ones to a specific study with a permission role. The user provides the email of an investigator that triggers an auto generated email to that email. Upon receipt, investigators need to confirm the email and follow a registration. This list can be then exported to an excel, as depicted in Figure 33.

gaserpolating infordation print au CREATE USER graditas ginno actions print au information print au hopdanaker ginno actions print au information print au information print au information print au informat	teemer								📫 🖂 🚺 lii	da Manika 👻	
• DASECONDU • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC • DASECONDUC <th>USER MANAGEN</th> <th>MENT</th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th>	USER MANAGEN	MENT									
• statis > Six: • statis • Rel • rel • Rel • Rel • Rel • Instatis	ker 🗸										
Loss Loss Loss Enal Address Loss Enal Address Loss Enal Address Loss Comparison Loss<											
Loss find Address Encla Address Rele orgenization orgenization<	✓ Show: 10 ✓						Assign	User	Create User	🕹 Export	
User Introtections Email All Clinitization • ALERS operAlkBouzgeInnovationspirit.eu System Administrator Innovation Spirit Sto20/03/01/15/258 Clinitization • MARRS operAlkBouzgeInnovationspirit.eu System Administrator Innovation Spirit Sto20/03/01/05/258 Clinitization • Motificacioni operAlkBouzgeInnovationspirit.eu Application Innovation Spirit Sto20/03/01/02/030000 Clinitization • Outstackouse operAlkBouzgeInnovationspirit.eu Application Innovation Spirit Sto20/03/01/02/03/01/02/03/0000 Clinitization Innovation Spirit.eu Innovation Spirit.			. Dela	ô		<u> </u>			4 - til		
User involutions operAdeousginnovationspirit.eu	Email Address		~ KOIÐ	Urge	mzduon	, U	edted On	~	Actions		
Aussuit openpliniovationsprint.eu System Administrator innovation Sprint 2020/b/02,020000 Dist is image Norme-Attors openpliniovationsprint.eu Application innovation Sprint 2020/b/02,020000 Dist is image goburgoulozginiovationsprint.eu goburgoulozginiovationsprint.eu CELATE USER Image Image gonzkinzeginiovationsprint.eu Fini Name* Image Image innokaginiovationsprint.eu Fini Name* Image Image in			All	~					QIX		
opnownatikating/innovationspirit.eu gradinage/innovationspirit.eu gradinage/innovationspirit.eu innovationspirit.eu innovationspirit.eu <td< td=""><td>✓ aperikleous@inn</td><td>novationsprint.eu</td><td>System Administrator</td><td>Inno</td><td>vation Sprint</td><td>20</td><td>021/03/01, 15:27:58</td><td></td><td>🗹 l 🎝 l 💼</td><td></td><td></td></td<>	✓ aperikleous@inn	novationsprint.eu	System Administrator	Inno	vation Sprint	20	021/03/01, 15:27:58		🗹 l 🎝 l 💼		
CRESTORANCES gladropoulosginnovationspirit.zu CREATE USER Gradita gelinnovationspirit.zu gmatika gelinnovationspirit.zu Gradita gelinnovationspirit.zu Fini Nime** Imonika gelinnovatinspirit.zu Fini Ni	1 v apne@innovatio	nsprint.eu	System Administrator	Inno	vation Sprint	20	020/10/02, 03:00:00		🗹 🕹 🛅		
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gmdlkasginnovationspirt.ku Name *	glabropoulos@ir	nnovationsprint.eu								*	🖾 🚺 Irida Manika
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hopdanakegiinnovelionspiriteu seiset innaikagiinnovelionspiriteu foatik Adress * koatopoulougiinnovelionspiriteu Foatient * jyavitjuantaktmibwhgmitzortonline keis * jyavitjuantaktmibwhgmitzortonline keis * showing to 0 of 4 entries Steer	gmatikas@inno	vationsprint.eu									
Imanika gilinovationsprint.eu Imanika	hopdenakker@ir	nnovationsprint.eu	First Name: *		Last Name:*			0			
Ikotopulouginnovationspiriteu Ime izeret Iyyvitijuumäkämävitionine Relet Insektion Ime izeret Showing 1 to 10 of 14 entries Relet	imanika@innova	ationsprint.eu	Empil Address: *		Password						
Ignority/purplex	kkostopoulou@i	nnovationsprint.eu		3							
Showing I to 10 of 14 entries			Role: *				Time Zone: *				
Showing I to 10 of 14 entries	iyzvvtrjuamokon	nown@mnzayt.oniine	Select				Select				
tare in vester fare	Showing 1 to 10 of 14	lentries	Stos:								
correct lo											
	ion Sprint										Cancel 8 Submit





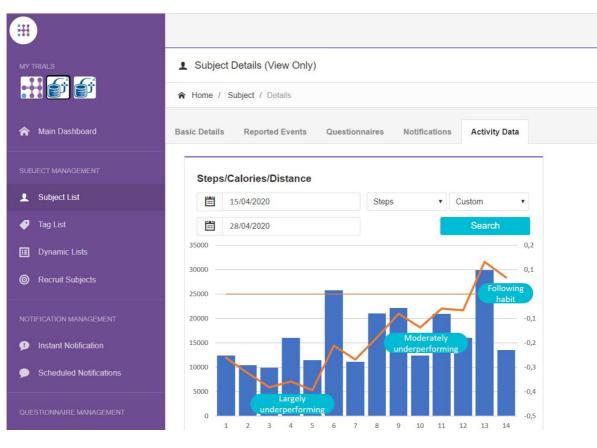
10 AI MODULE

10.1 DEEP PHENOTYPING

Further to the currently supported features of Healthentia, i.e. collecting data from patients and making it available to an EDC for further statistical evaluation, the wealth of information collected is used in real time by the Healthentia AI/ML module to create clusters of patients' phenotypes and provide useful insights for clinical endpoints. Based on the patients' vector data, we create behavioural phenotype models and we cluster patients' profiles into them. Using the clustering mechanism, we can characterise patients' habits and detect deviations from them to generate alarms. The clustering of patients into to behavioural phenotypes creates a valuable content to associate them with drug efficacy and support the self-configured adaptive trials. Finally, AI/ML algorithms can train models to predict outcomes, e.g. VAS, QoL, bleedings, falls, before the patients report them, by feeding the system with the automatically collected vectors.

10.2 PREDICTION SERVICES

The deep phenotyping process described in the previous section, enables a number of forecasting services, among them the ability to predict study endpoints, or behavioural biomarkers. In Figure 34, one can see how activity patterns are recognized and characterized, while the system is able to provide predictions or alarms.









Further to the patter detections, the system uses AI/ML algorithms to break down the distribution of several behavioral biomarkers and evaluate their prediction capacity; see Figure 35 and Figure 36.

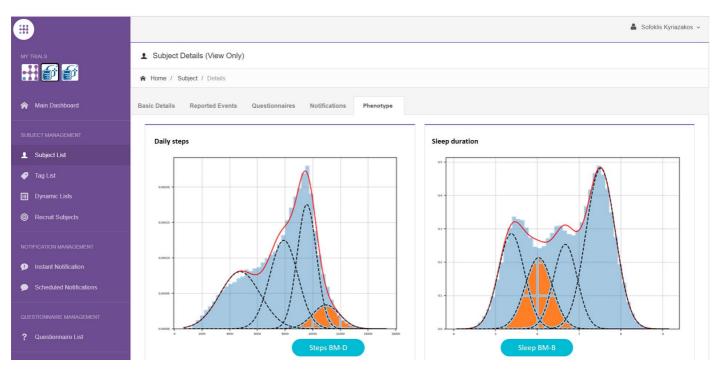
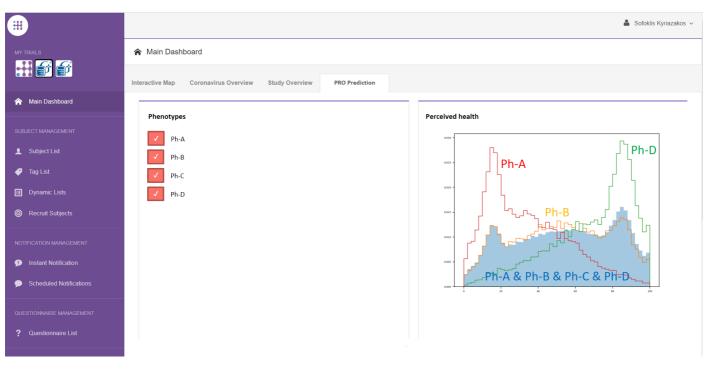


Figure 35: Distribution of activity biomarkers







11 AUDIT TRAIL

11.1 PORTAL LOG

In the section of Log Management all actions that users do from viewing to editing or deleting. The log list of actions can be filtered by date from the top of the page, while each column on the table allows the search for a specific result. You can also short by alphabetic or numeric order per column. When viewing the log details you can get more information on the reported action. As in all sections of the portal all data are exportable to an excel file.

Healthentia Real World Outcon	nes	PORTAL LOG				🕻 🛛 🦝 Konstantina Kostopoulou 🗸	
Symptom Tracker					Log Details		
A DASHEGARD					A Home / Log / Details		
L SUBJECTS		Show: 10 🗸					
L USERS		Email 0	Role 0	Description			
ALERTS					Email:		Role:
0 ECONSENT		e.g.: someone@example.com	Select 🗸	e.g. View list of	palak@evincedev.com		Admin
		gmatikasginnovationsprint.eu	System Administrator	Logout by: gmatikasglinnovationsprint.eu on 19/05/2021 19:31:40.	Action Performed:		Time Stamp:
		gmatikas@innovationsprint.eu	System Administrator	View Details of Subject Id:5C9AA by: gmatikas@innovationsprint.eu on	View Details of Patient		05/12/2018 10:11:01
		gmatikasginnovationsprint.eu	System Administrator	View List of Subject by: gmatikas@innovationsprint.eu on 19/05/2021 18	Description:		
CO AUDIT TRAL		gmatkasglinnovationsprint.eu	System Administrator	View List of Subject by: gmatikas@innovationsprint.eu on 19/05/2021 18	View Details of Patient Id:14c0cb00-1e49-4d0	0-8231-01c30fd3e158 by: palak@evincedev.	.com on 05/12/2018 10:11:00.
Portal Log		gmatikas@innovationsprint.eu	System Administrator	View List of Subject by; gmatikas@innovationsprint.eu on 19/05/2021 18			
		gmatikas@innovationsprint.eu	System Administrator	View List of Subject by: gmatikas@innovationsprint.eu on 19/05/2021 16			Back 🔇
		gmatikas@innovationsprint.eu	System Administrator	View List of Subject by: gmatikas@innovationsprint.eu on 19/05/2021 18			
		gmatikas@innovationsprint.eu	System Administrator	View List of Subject by: gmatikas@innovationsprint.eu on 19/05/2021 18	3417. View List of Subject	19/05/2021, 21:34:17	
		gmatikasglinnovationsprint.eu	System Administrator	View List of Subject by: gmatlkas@innovationsprint.eu on 19/05/2021 18	3435. View List of Subject	19/05/2021, 21:34:15	
		gmatikas@innovationsprint.eu	System Administrator	View List of Subject by: gmatikas@innovationsprint.eu on 19/05/2021 18	3434. View List of Subject	19/05/2021, 21:34:14	
		Showing 11 to 20 of 2,118 entries				+ 1 2 3 4 5 212 →	

Figure 37 Log Management & Details

11.2 APPLICATION LOG

The application log, provides information about the actions of the subjects, e.g. their participation in questionnaires, as shown in Figure 38

				🧬 🛔 Sofoklis Kyriazakos 🗸					
MY TRIALS	XXX Application Log								
	A Home / Application Log	R Home / Application Log							
🏫 Main Dashboard									
	Show: 10 ¥			X Clear Search Filters 📑 Export data to excel					
	Subject ID 0	Description 0	Log Type 🗘	Timestamp ~					
🥏 Tag List	e.g: 123456001	e.g.: Login Failed	- Select -	27/04/2020					
11 Dynamic Lists	6CEFC	initial COVID-19 Assessment	Questionnaire	27/04/2020, 17:36:24					
Recruit Subjects	HTAXE	Abdominal pain	Questionnaire	27/04/2020, 15:08:36					
NOTIFICATION MANAGEMENT	HTAXE	Diarrhea	Questionnaire	27/04/2020, 15:08:30					
Instant Notification	HTAXE	Nausea	Questionnaire	27/04/2020, 15:08:24					
Scheduled Notifications	HTAXE	Muscle Pain	Questionnaire	27/04/2020, 15:08:19					
	H1AXF	Headache	Questionnaire	27/04/2020, 15:08:04					
? Questionnaire List	H1AXF	📑 Fatigue	Questionnaire	27/04/2020, 15:07:51					
: Quesuonnaire List	HIAXF	B Difficulty of breathing	Questionnaire	27/04/2020, 15:07:39					
USER MANAGEMENT	H1AXF	E Cough	Questionnaire	27/04/2020, 15:07:31					
👤 User List	H1AXF	B Oxygen saturation	Questionnaire	27/04/2020, 15:07:23					
INVITATIONS MANAGEMENT	Showing 1 to 10 of 942 entries			⊢ 1 2 3 4 5 _ 95 →					

Figure 38 Application Log Details