



TrialFinance Manager

Entscheiderfabrik 15.02.2024

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Projektpartner Landesklinik Salzburg Prof. Dr. F. Lagler, CEO CRCS

Clinical Research Centrum Salzburg GmbH HEALEX



Klinische Arzneimittelprüfungen in Österreich (Quelle Pharmig)

UNIKLINIKUM SALZBURG

Verteilung von laufenden klinischen Prüfungen pro Bundesland 2021 in Österreich*



*Angaben zu 76% der klinischen Prüfungen erfolgt. | Angaben in Absolut Die meisten laufenden klinischen Prüfungen in Österreich sind multinational und multizentrisch, d. h. eine klinische Prüfung kann in zwei oder mehr Bundesländern bzw. Zentren laufen.

Durchschnittliche Anzahl von Studienteilnehmer:innen in laufenden klinischen Prüfungen pro Bundesland 2021 in Österreich*



*Angaben zu 62% der klinischen Prüfungen erfolgt. | Angaben in Absolut

SALZBURGER LANDESKLINIKEN – CRCS – Paracelsus Medizinische Privatuniversität



Clinical Research Centrum Salzburg GmbH HEALEX





X 100 -

250

Studien

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Typische Studienzentrumsbudgets

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C.d.	Praardare	*1,	**	Padgel	•	57	C104	C101	C201	C104	C40-1	C50-1	C691	C784	CID1	C104	C1101	C1101	C1201	C1301	C1401	47638	
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INCEX	Eligibility Collects	,	•	\$3,88	53,00	53,81																	Augusta Baradas Calata & Baltinean (BBC187), BI
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	loada, 12 load ECG, 12-load ECG: Includes loading, interpretation and report	28	•	74,00		20,00	24,00		24,00	24,00	201	74,00	24,00	201	24,11	24,00	74,00	201	26,00	24,00	24,00	Fina	Henris HARDE alterit eniterit anteentet ter, eniterit Konpeleret en temperate, ettema, ettema (Kel Ber alt ember Landerta
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HPIEZE	Physician, Complex (e.g. initial stati), final stati) - Per Visit	23,5	•	151,11	151,11	61,11	151,01	61,11	631,00	451,11	151,11	151,11	491,11	151,01	151,11	150,00	51,0	61,11	151,11	51,0	151,11		Interpretation and Reports Magnets common angles, a
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HPH24	Pro Visit Harne, Campleo Ir.a. (a)Rabaiail, Gaalaiaill (Pro Visit	14.5		213,00	10.0	103,50	103,58	93,51	10.51	103,51	103,50	113,58	10.51	103,50	99,91	103,50	103,50	93,51	103,50	10,51	10,51	13198	Interpretation and Reports Meaneds accounter any age of
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	Casta alla 48				763,58	1987,58	836,58	\$38,58	883,58	1113,51	113,51	883,58	883,58	113,51	883,58	113,51	003,50	113,51	883,58		113,51		Interpretation and Reports Magnets accounts any age of

- 21 verschiedene obligate Leistungen zu 31 Zeitpunkten

- 82 bedingte Leistungen
- bei 15 Teilnehmerinnen ca. 1.000 bis 2.000 Leistungen an bis zu 400 d

von Studienzentrum, Radiologie, Pathologie, Labor, Kardiologie, Augen ...

Fazit



- 1. Manuelle Erfassung der Leistungen in unterschiedliche Exceltabellen;
- 2. Menschliche Eingabefehler;
- 3. Keine Transparenz, wann welche Zahlung fällig ist;





Wie haben wir die Herausforderung gelöst?

HEALEX



				- 4	0	TI	T2	F1	F2	F3
Activity/ Assessment	CRF (Y/N)	Staff Member	Approximate Time to Complete	Pre-Study Screening/ Consent	Pre-Study Baseline/ Randomization	Study Visit 1	Study/ Interim Visit 2 and/or 2 Wk Interim	Follow-Up 2-Months	Follow-Up 4-Months	Follow-Up 6-Months
Pre-Screening Consent	No CRF	Study Coordinator	5 Minutes	x						
Screening Log	No CRF	Study Coordinator	5 Minutes	x						
Consent Form/Quiz	No CRF	Study Coordinator	45 Minutes	x						
Inclusion/ Exclusion Form	CRF	Study Coordinator	NA	x						
Urine Screen	CRF	Study Coordinator	10 Minutes		x		x	x	x	x
Locator Form	No CRF	Interviewer	10 Minutes		x		Update X	Update X	Update X	
Demographics Questionnaire	CRF	Interviewer	10 Minutes		x					
Addiction Severity Index (ASI) LITE	CRF	Interviewer	45 Minutes		x			x	×	x
Composite International Diagnostic Interview (CIDI) HIV Risk Behavior	CRF	Interviewer	45 Minutes		x					
Survey (RBS) Timeline Follow Back	CRF	Interviewer	15 Minutes		x			×	×	x
(TFB)	CRF	Interviewer	5 Minutes				X	X	X	X
Self-Efficacy	CRF	Interviewer	5 Minutes		X		X	X	X	X
Randomization	CRF	Study Coordinator	15 Minutes		x		-			
Voluntary Blood Draw C&E [Counseling and Education Intervention] Th [treatment] Group	CRF	Study Phiebolomist	15 Minutes			x				x
All Groups, Optional. Blood Draw at Study Close	CRF	Study Phiebotomist	15 Minutes							x
Termination Form	CRF	Study Coordinator	NA							x
SAE [Serious Adverse Event] Form	CRF	Study Coordinator	NA	As Needed T	hroughout Protoc	ol				
Progress Notes	No CRF	Al Team Members	NA	x	x	x	x	x	x	x
Communication Log	No CRF	Al Team Members	NA	Every Phone	or In-Person Cont	act Outside of	a Regular Visi			

HIV/HCV Risk Reduction Protocol Schedule of Forms and Procedures

[CRF: case report form]"181 [Reproduced from original table]

HEALEX

Schritt 1 Eingabe Studienprotokoll						
	test 🕥 \Lambda 🖻 Max Mustermann 🗸	Lizenz-Typ: Test Version: 2023.11-lat				🚍 🖪 Abrechnung
		axa ⊼				< 🖾 Studie A
				Visitenplan	udienleistungen	Patienten Erbringerleistungen St
	× Ū 🔪	Interval: 0 Tolerance: 0		ISE Baseline Visit	.a - ⊞	Visit type Scheduled
	× 🖻 🔪	Interval: 3 Tolerance: 0	Ref.: BASE	OS1 Dosing Visit 1	id ≁ ‼	
	× Ū 🔪	Interval: 2 Tolerance: 1	Ref.: DOS1	Dosing Visit 2	u ≁ ‼	
	×ŪŃ	Interval: 2 Tolerance: 1	Ref.: DOS2	Dosing Visit 3	ia ≁ ‼	
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	× 🗇 🔨	Interval: 14 Tolerance: 2	Ref.: BASE	SS Assessment Small	ya ≁ ‼	
	× Ū 丶	Interval: 3 Tolerance: 1	Ref.: ASSS	DSS Dosing Visit 5	id ≁ ‼	
	× 🗇 💊	Interval: 2 Tolerance: 1	Ref.: DOS5	DS6 Dosing Visit 6	g ≁ ‼	
	× 🗇 🔨	Interval: 2 Tolerance: 1	Ref.: DOS6	DS7 Dosing Visit 7	a ≁ ‼	
	× 🗇 💊	Interval: 3 Tolerance: 1	Ref.: DOS7	DS8 Dosing Visit 8	og → ‼	
	× 🗇 🔨	Interval: 28 Tolerance: 2	Ref.: BASE	SL Assessment Large	ya + ‼	
Schritt 2						

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Eingabe Visitenplan



hritt	3					
ingabe agsdat ienleist	en / ung					
				Lizenz-Typ: Test	Version: 2023.11-latest	(?) A P Max Mustermann V
A					★ EXPOR	T STUDY SERVICES NEUE VISITE
tungen Stu	dienleistungen Vis	itenplan				
•	II 👻 BASE	Baseline Visit		Interval: 0 To	olerance: 0	
	₩ * DOS1	Dosing Visit 1	Ref.: BASE	Interval: 3 To	olerance: 0	✓ □ ×
	∷ v DOS2	Dosing Visit 2	Ref.: DOS1	Interval: 2 To	olerance: 1	✓ □ ×
	∷ v DOS3	Dosing Visit 3	Ref.: DOS2	Interval: 2 To	olerance: 1	✓ □ ×
	∷ v DOS4	Dosing Visit 4	Ref.: DOS3	Interval: 3 To	olerance: 1	✓ □ ×
	∷ × ASSS	Assessment Small	Ref.: BASE	Interval: 14 To	olerance: 2	✓ □ ×
	∷ v Doss	Dosing Visit 5	Ref.: ASSS	Interval: 3 To	olerance: 1	✓ □ ×
	∷ ▼ DOS6	Dosing Visit 6	Ref.: DOS5	Interval: 2 To	olerance: 1	✓ □ ×
	∷ ▼ DOS7	Dosing Visit 7	Ref.: DOS6	Interval: 2 To	olerance: 1	✓ □ ×
	∷ ≖ DOS8	Dosing Visit 8	Ref.: DOS7	Interval: 3 To	olerance: 1	✓ □ ×
	II - ASSI	Accessment I arge	Pof-RASE	Interval-28 Ti	oloranco: 2	∠ □ ×

Schritt 3 Eingabe Eingabe Vertragsdaten / Studienprotokoll Studienleistung E Abrechnung Lizenz-Typ: Test Version: 2023.11-latest (?) 🗛 📵 Max Mustermann 🗸 E Katalog für Erbringer Q Suche nach Providern NEUER ERBRINGER < BEZEICHNUNG BESCHREIBUNG EXTERN STUDIE KOSTENSTELLE Clinic Internal Internal clinic administration No 111 Clinic Laboratory Internal Laboratory No 222 Labor Dr. Wisplinghoff Labor Dr. Wisplinghoff, Junkersdorf Yes 333 Labor Elisabethkrankenhaus Standard Radiologie für MERCK Studien Yes 666 MVZ: Medizinisches Zentrum für bildgebende Diagnostik Yes 444 MVZ Strahleninstitut Ð Unsere Standard Radiologie Yes Radiologie & Nuklearmedizin am Ebertplatz **B** Research Center 2 RC für Klinikum No JUNITIC 4 Eingabe Eingabe Visitenplan Der Dienstleister





Studie ist für die Rekrutierung bereit!





Schritt 1 Patient wird	Schritt 3 Erfassung der									
angelegt	= 🖸 TrialFinance			Lizenz-Typ: Test	Max Mustermann	n 🗸				
	< ট Aufnahme	Q Suche nach Visiten	Datum der Suche			NEUEN ZEITPLAN HINZUFÜGEN AUSSERPLA	AUSSERPLANMÄSSIG HINZUFÜGEN ENDE			
	 Studie A A123456 									
	Zeitplan für Patient	VISITE	C	DATUM						
i	•	Baseline Visit		01.02.2024	8			ĉ	ć	
		Baseline Visit				Notizen				
		Assent form, if applicable				NA	\otimes		11	
		Body Measurements		01.02.2024	8	Notizen				
		Concomitant Illness & Medical History				Notizen				
		Concomitant Medication				Notizen				
		Demography	 (01.02.2024	8	Notizen				
		Details on Haemophilia & Haemomphilia Treatment History				Notizen				
		Eligibility Evaluation	 (01.02.2024	8 🖬	Notizen				
		Inclusion / Exclusion Criteria				Notizen				
		Informed Consent				Notizen				
	Schritt 2 Visite wird erfasst									

Schritt 3 Schritt 1 Erfassung der Patient wird erbracht<u>e</u> angelegt Leistung Intern н. = 🖸 TrialFinance (?) Max Mustermann V Lizenz-Typ: Test 芹 Aufnahme Q Suche nach Visiten < Datum der Suche AUSSERPLANMÄSSIG HINZUFÜGEN ENDE DER STUDIE Studie A < A123456</p> Zeitplan für Patient DATUM VISITE 01.02.2024 🚫 🖬 🗌 ð Baseline Visit **Baseline Visit** 🔽 01.02.2024 🚫 🖬 Notizen NA NA \odot Assent form, if applicable 🚫 🖬 🛛 Notizen 01.02.2024 Body Measurements 🚫 🖬 🛛 Notizen Concomitant Illness & Medical History \checkmark 01.02.2024 8 Concomitant Medication \checkmark 01.02.2024 Notizen 01.02.2024 🛛 🔂 🖬 Demography \checkmark Notizen Schritt 4 Schritt 2 Quittierung der Visite wird Leistung zum erfasst Studienbüro





Erste Meilensteine können Abgerechnet werden?



HEALE[×]







Label:	Curren	t State:	Cutoff Date:		Target Date:	Inv	oice Num	ber:
Quarterly April-June 2024	draft	12.04.2024	31.03.2024		01.04.2024	no	one	
INVOICE ITEM / LABEL		STUDY SERVICES /	AMOUNT PER UNIT	1	QUANTITY / S	SUM		
1. Trial Setup Fee	1				1.000,00 €	1	H	×
2. Administrative Services	1				2.000,00 €	1	H	×
3. Blood Small	1	Blood Small	110,00 €	8	880,00 €	0	H	×
4. Blood Large	1	Blood Large	140,00 €	7	980,00 €	\odot	H	×
5. Assessment Small	1	Assessment Small	300,00 €	2	600,00 €	0	H	×
6. Assessment Large	1	Assessment Large	450,00 €	2	900,00 €	0		×
7. Baseline Visit	1	Baseline Visit	500,00 €	3	1.500,00 €	0	H	×
8. Dosing Visit 1	/	Dosing Visit 1	130,00 €	3	390,00 €	0		×
9. Dosing Visit 2	/	Dosing Visit 2	130,00 €	3	390,00 €	0	H	×
10. Dosing Visit 3	/	Dosing Visit 3	130,00 €	2	260,00 €	0		×
11. Dosing Visit 4	1	Dosing Visit 4	130,00 €	2	260,00 €	0		×





HEALE[×]





Rechnung wurde erstellt

TrialFinance-Management Report

HF∆I F**∛**

=	Billing							Version	n: latest 🕐 🖪	P S User Name 🗸
<	General Payme	ent Report 202	23							
	TRIAL	SPONSOR		JAN	FEB	MAR	APR	МАУ	JUN	TOTAL
Ĩ.	MII Kerndatensatz	Sponsor1	Ę	3.500 EUR, (7 Visits)	3.000 EUR, (6 Visits)	2.000 EUR, (4 Visits)	3.000 EUR, (6 Visits)	500 EUR, (1 Visit)	0 EUR, (0 Visits)	12.000 EUR, (24 Visits)
			R	500 EUR, (1 Visit)	1.500 EUR, (3 Visits)	3.500 EUR, (7 Visits)	2.500 EUR, (5 Visits)	5.500 EUR, (11 Visits)	0 EUR, (0 Visits)	13.500 EUR, (27 Visits)
Ĩ	CODEX	Sponsor 2	Ę	4.800 EUR, (8 Visits)	3.600 EUR, (6 Visits)	1.800 EUR, (3 Visits)	1.200 EUR, (2 Visits)	0 EUR, (0 Visits)	0 EUR, (0 Visits)	11.400 EUR, (19 Visits)
			R	0 EUR, (0 Visits)	3.000 EUR, (5 Visits)	5.400 EUR, (9 Visits)	7.800 EUR, (13 Visits)	9.000 EUR, (15 Visits)	0 EUR, (0 Visits)	25.200 EUR, (42 Visits)
Ĩ	ReLApsE	Sponsor 1	Ę	4.000 EUR, (10 Visits)	3.600 EUR, (9 Visits)	2.000 EUR, (5 Visits)	1.600 EUR, (4 Visits)	1.200 EUR, (3 Visit)	0 EUR, (0 Visits)	12.400 EUR, (31 Visits)
				1.200 EUR, (3 Visits)	1.600 EUR, (4 Visits)	2.800 EUR, (7 Visits)	4.800 EUR, (12 Visits)	4.800 EUR, (12 Visits)	0 EUR, (0 Visits)	15.200 EUR, (38 Visits)
ĩ	GMMG-CONCEPT	Sponsor 3	Ę	5.000 EUR, (10 Visits)	5.000 EUR, (10 Visits)	3.500 EUR, (7 Visits)	1.500 EUR, (3 Visits)	2.500 EUR, (5 Visit)	0 EUR, (0 Visits)	17.500 EUR, (35 Visits)
				1.000 EUR, (2 Visits)	3.000 EUR, (6 Visits)	4.000 EUR, (8 Visits)	7.000 EUR, (14 Visits)	9.000 EUR, (18 Visits)	0 EUR, (0 Visits)	24.000 EUR, (48 Visits)
									Records per	rpage: 20 🔻 1-4 of 4
	TOTAL Values		Ę	17.300 EUR, (35 Visits)	15.200 EUR, (31 Visits)	9.300 EUR, (19 Visits)	7.300 EUR, (15 Visits)	4.200 EUR, (9 Visits)	0 EUR, (0 Visits)	53.300 EUR, (109 Visits)
	Total Amount: 131.200 EUR	2								
	Total Visits: 264									
			R	2.700 EUR, (6 Visits)	9.100 EUR, (18 Visits)	15.700 EUR, (31 Visits)	22.100 EUR, (44 Visits)	28.300 EUR, (56 Visits)	0 EUR, (0 Visits)	77.900 EUR, (155 Visits)

Was haben wir dank Ihrer Hilfe erreicht? HEALEX

Nr.	Prozess Paket		Beschreibung						
1	Studien Idee	TrialSponsor	Studien-ID, Studysite managment / C.V-management Portalfunktionalitäten zur Ausleitung auf der Webseite. Site Qualifizierung.						
2	Studienanlagen TrialSpons		Studiendokumente werden im eigenen Workspace bearbeitet, Lesebestätigung.						
3	Kostenschätzung TrialBudge		Vollkostenkalkulation nach EU-Richtlinie Zur Verhandlung mit dem Sponsor und interne Freigabe						
4	Drittmittelanzeige	TrialNotice	Schnelle & effiziente und fehlerfreie Erstellung der Drittmittelanzeige nach HG § 71 Abs. 3						
5	Studiendesign	TrialComplete	Initiierung der Studie im EDC Planung Probandenzahlen und durchzuführende Prozeduren Visitenplan an SMA Billing für Setup Billing						
6	Studiendurchführung	TrialComplete	Dokumentation der Durchführung von Studienvisiten						
7	Studienabrechnung	TrialFinance	Interne Leistungsverrechnung (Apotheke, Röntgen, Labor) Externe Leistungsabrechnung / Liquiditätsmanagement SAP-Abrechnung						
8	StudienexportTrialCompleteTrialSponsor		Export nicht-Probandendaten (Trial Master File) Export Probandendaten (PDF-Booklets) Export an Drittsysteme						
9	Studienarchivierung	TrialArchive	Archivierung der Studiendaten für vertraglich vereinbarte Dauer						





Herzlichen Dank für Ihr Interesse

Für mehr Informationen:

www.healex.systems