




THROMBOREDUCTIN REGISTRY CALCULATION OF COSTS

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DOCUMENT STRUCTURE

Changes

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02.09.2010	Vít Kandrnal	1.01	Document Creation
02.09.2010	Petr Brabec	1.02	Minor amendments

Reviewers


Name	Company
Doc. RNDr. Ladislav Dusek, Ph.D.	Director of IBA MU
Petr Brabec, MS.c.,	Deputy director of IBA MU

Principle

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		Revision no. : 1.02
		Copy no. :
		Print date :

CONTENT

1. Introduction	4
Requested services	4
2. Operating costs per year	5
2.1 FIXED COSTS PER YEAR	5
2.2 ESTIMATED VARIABLE COSTS PER YEAR	5
TOTAL COSTS	6

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		Revision no. : 1.02
		Copy no. :
		Print date :

1. Introduction

Requested services

Institute of Biostatistics and Analyses, Masaryk University Brno, (hereinafter "IBA MU") agreed to provide services specified below to AOP Orphan Pharmaceuticals AG (hereinafter AOP) during period between 01. 09. 2011 and 30. 04. 2013 in conjunction with the following project:

"Registr pacientů s dg. Esenciální trombocytémie a trombocytémie provázející jiné myeloproliferativní onemocnění léčených Thromboreductinem®"


Requested services:

- Assistance with project administration and management (includes necessary phone calls, emails and meetings with AOP representatives, response to queries from AOP representatives as well as participating doctors and principal investigator, necessary communication with database provider).
- Administration of investigator fee payments which includes:
 - Sending a letter to participating doctors explaining the change of provider
 - Arranging contracts with all participating doctors
 - Annual payment of investigator fees (including bank transfer fees)
 - Management of contact details database and its quarterly update
- Data validation = forms and data check, generation of queries and liaison with the centre, collection of missing data,
- Digitalization maximum of 820 forms 1x per year
- Statistical analysis 1x per year
 - Core statistical analysis (ca 50-60 hours)
 - Additional analysis (15 hours)
 - Analysis for publication in an international scientific magazine with an impact factor.
- The cost calculation also include estimation of investigators fee for each year (2011 + 2012)

Items which are **not included**:

- On demand analysis related to the project which is not included in the core analysis, additional analysis and analysis for impact publication as stated above. (In that case cost will be calculated as follows= **number of hours x 850,-Kč (hour rate) x 0.7** (discount factor due to reduced time cost for additional analysis).

Date of issue : 26.10.2016	Author : Vít Kandmal	Page 4 (total 6)
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		Revision no. : 1.02
		Copy no. :
		Print date :

2 Operating costs per year

2.1 FIXED COSTS PER YEAR

1	Project administration and management including annual project report	37 000,-Kč
2	Communication with centres (125) – information mail about change of provider (2011 only)	4 000,-Kč
3	Actualization of contact details, calculation of investigators fee, collecting sum confirmation from each doctor; 150,- Kč per investigator	18 750,-Kč
3	Contracts with investigators (125); 200,-Kč pre investigator	25 000,-Kč
4	Investigator fees payments according to the contract (SOD) (125) 550,- Kč per investigator	68 750,-Kč
5	Recorded delivery mail confirmation following successful payment (125) 80,-Kč per investigator	10 000,-Kč
6	Data validation	48 000,-Kč
7	Annual statistical analysis	53 000,-Kč
TOTAL per year*		264 500,-Kč

*VAT is not included


2.2 ESTIMATED VARIABLE COSTS PER YEAR

	Item	Per record	No of records	Total
2				
3				
TOTAL per year				

*VAT is not included

**Exact sum will be calculated according to the actual number of forms digitalized and paid for.

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		Copy no. :
		Print date :

TOTAL COSTS

Total Costs – 2011		264 500,-Kč
1	Fixed costs (2.1)	
2		
TOTAL 2011*		
Total Costs – 2012		260 500,-Kč
1	Fixed costs (2.1) – (except 2.1.1)	
2	Variable costs – estimation**	
TOTAL 2012*		
TOTAL 2011 +2012*		

*VAT is not included

** Exact sum would be calculated according to the actual number of CRFs which will be validated

MUDr. Vít Kandrnl
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