



# THROMBOREDUCTIN – COST CALCULATION

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**Author:** Michaela Jelínková  
**Approved by:** Petr Brabec  
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## 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. 2016 and 30. 6. 2017 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, necessary communication with database provider).
- Query management
- Pharmacovigilance
- 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 of approximately 1200 forms.
- Statistical analysis 1x per year
  - Core statistical analysis (approx. 90 hours)
  - Additional analysis **could be invoiced separately**
  - Analytical support for Principal investigators (prof. Penka and Schwarz)
  - Analysis for publication in an international scientific magazine with an impact factor.

## 1.1. OPERATING COST

### FIXED COST PER YEAR

	Item	Per Investigator/hour	No of Investigators/ hours	Total
1	Project administration and management			41 000,- CZK
2	Communication with centres			4 000,- CZK
4	Contracts with investigators, calculation of investigators fee, collecting sum confirmation from each doctor			29 000,- CZK
5	Investigator fees payments according to the contract (SOD)			73 150,-CZK
6	Recorded delivery mail confirmation following successful payment			10 640,-CZK
7	Data validation and Annual statistical analysis			150 000,-CZK
	<b>TOTAL per year*</b>			<b>307 790,- CZK</b>

\*VAT is not included

### VARIABLE COSTS PER YEAR

	Item	Per record	No of records	Total
1	Queries - estimation**			70 000,-CZK
2	Pharmacovigilance - estimation**			82 500,- CZK
3	Data digitalization - estimation**			206 250,- CZK
	<b>TOTAL*</b>			<b>358 750,- CZK</b>

\*VAT is not included

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

## 2.3 TOTAL COST - SUMMARY

### 2.3.1 Total cost

1	Fixed costs	307 790,- CZK
2	Variable costs – estimation**	358 750,- CZK
<b>TOTAL per year</b>		<b>666 540,- CZK</b>