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Societal and economic impact of Accelerator Mass spectrometry

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Averting delay, attrition rate and R&D costs analysis of the implementation of Accelerator Mass spectrometry (AMS) in medicine development.

The model-based analysis of averting delay in medicine development and attrition rates will compare a base case model of medicine development to an adapted model including the AMS to determine its monetary value and potential societal impact. To determine the effects on costs and price, a base case model is made using multiple data sources and following the principles of costs and price determination of the Fair Medicine model©. This document is written by Fair Medicine, commissioned by TNO. This version of the document will serve as a basis of discussion on the analysis and outcomes. Reproduction of text or figures are only permitted with complete referencing to this report.

AMS implementation in medicine development

In order to assess the effect of AMS implementation, five key points are described and modelled in addition to the base case model. The assumptions and modelled adaptations are as follows:

1; In the classical model of medicine development human metabolite studies are performed in phase II. The results of the study are available in phase III. On average in 20% of the projects, a previously not described metabolite is found. To advance the project, a new animal study has to be done to assess this new metabolite. This will cause a delay because the project can only advance into the approval phase if the uncertainty of the metabolite(s) is resolved.

2; The delay is dependent on the type of product and is estimated to be between 12 and 24 months. A delay of 12 months will results in additional out-of-pocket expenses of 200k (USD) and a 24 months of delay has additional out-of-pocket expenses of 500k (USD). These assumption are based on knowledge from within TNO. We assumed that the distribution between the average occurrence of delay is equal between the 12 months and 24 months scenario.

3; Because of the different risk category of the AMS compared to the classical methods, the AMS makes it possible to perform human metabolite studies in phase I. Results of this study will be available in phase II. Because of the use of AMS any previously not described metabolite will not cause a delay.

4; The AMS human metabolite study can be added into an existing trial in phase I instead of a separate trial in phase II. It is assumed that this will save 750k on average after the addition of the added costs of the additional animal metabolite study.

5; Based on the knowledge of Fair Medicine, it is assumed to be likely that there will also occur a failure shift from phase III to phase II. The failure shift occurs because projects for which an unexpected metabolite is found might be a reason for failure in a small percentage of the failures that occur in phase III. These failures will occur in phase II instead of phase III, and therefore prevent unnecessary costs in Phase III.

All financial outcomes are shown in 2017 US dollars.

Model description

The base case scenario includes a total timeline of 11,5 years from pre-clinical to approval[2] and costs of 199mln USD out-of-pocket investments in the successful product[3]. The cumulative success rate is 2,20% including pre-clinical development and approval[3]. For all scenario's the same weighted average costs of capital (WACC) of 8.5%[1] is used because this is dependent on the financial market and industry as a whole and not indication-specific.

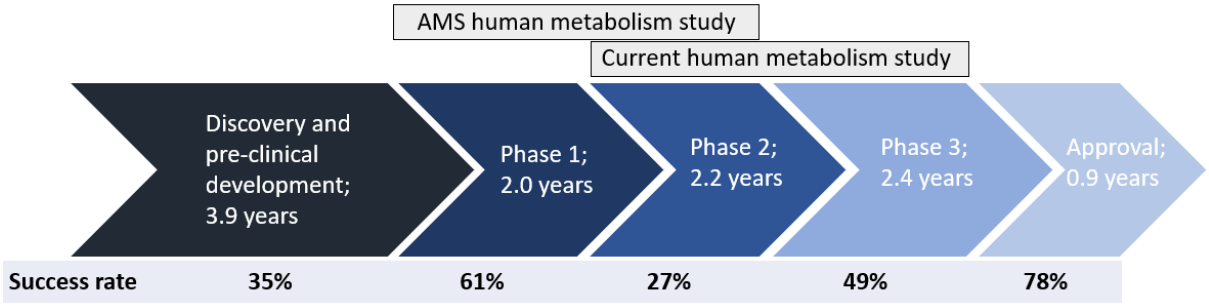

Figure 1: Base case development timeline and chance of success.

The weighted average R&D costs are 3.302mln USD, this is shown in figure 3. The out-of-pocket success costs are; 199mln USD (6%), costs of failure; 1.547mln USD (47%) and costs of capital; 1.547mln (47%).

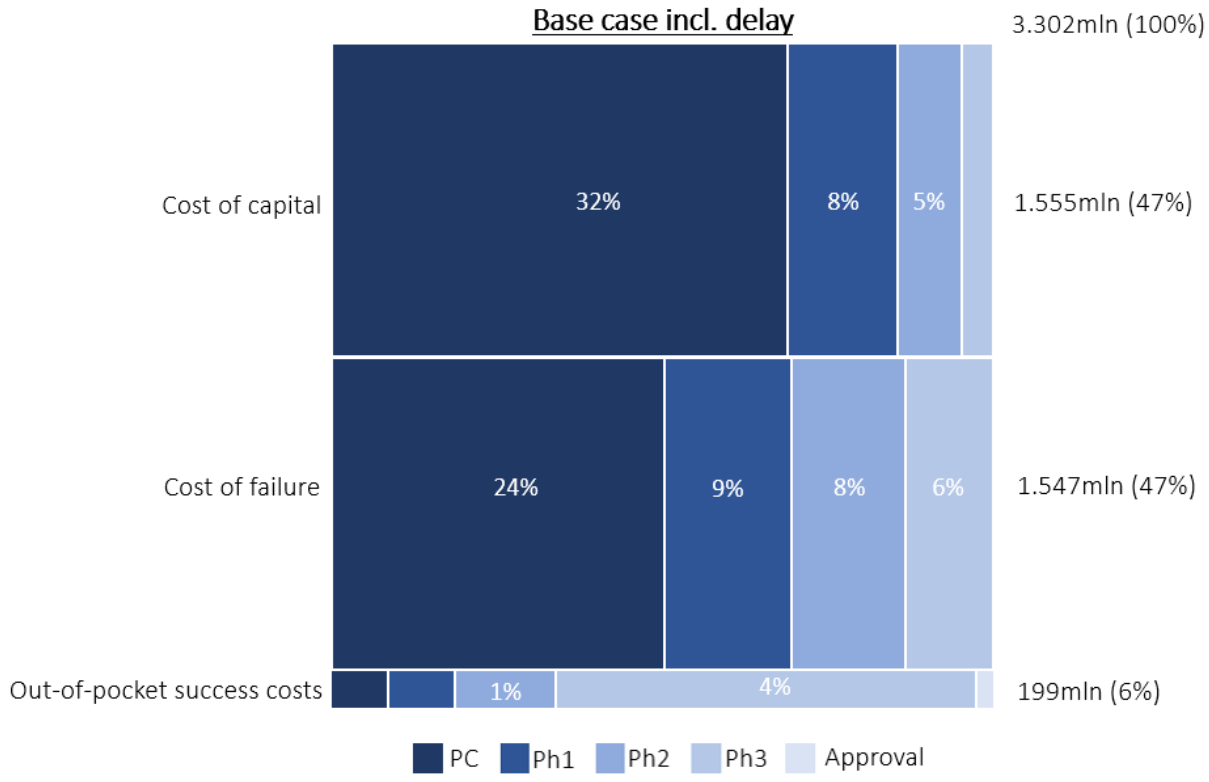

Figure 3: Base case modelled outcomes including a 20% chance of delay.

AMS implementation

The primary effect of implementation of AMS in medicine development is the costs reduction in phase I and averting delay in phase III. Implementation reduces the total R&D costs per NME from 3.302mln USD to 3.193mln USD saving 109mln (-3%) USD on average. The largest part of the costs reduction can be attributed to the lower accumulation of costs of capital as a result of the lower shorter development timeline. The lower out-of-pocket costs and failure costs generate a small portion of the savings caused by the direct savings of AMS implementation. In its turn, this results in reduced costs of capital.

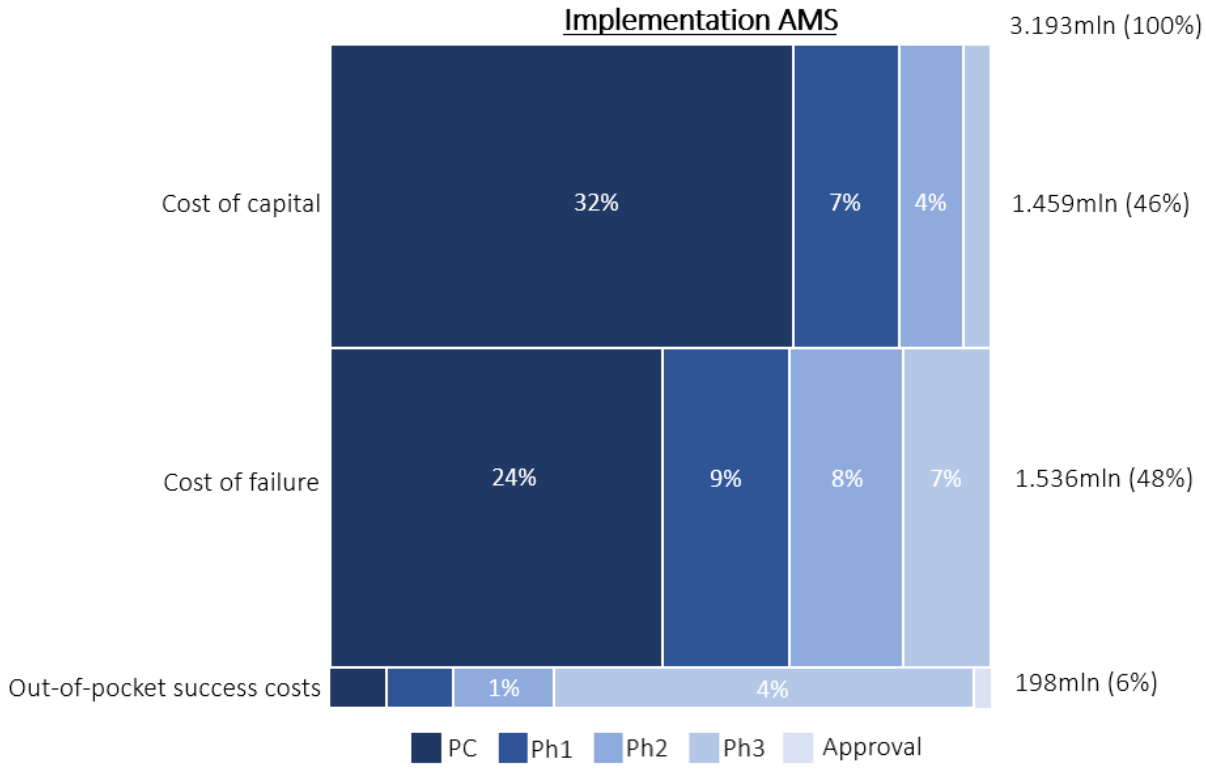

Figure 5: Modelled outcomes of implementation of AMS in the base case scenario.

Economic and societal impact

The analysis shows that implementation of the AMS in medicine development creates a monetary value of 109mln USD compared to the weighted average base case outcome. This is a reduction of 3%. The R&D costs reduction is primarily accounted to the cost of capital accumulated over product development time.

The total savings contribute to the total economic impact through an increased margin compared to the base case scenario by reduction of the cost of capital accumulation and costs of failure as a result of the failure shift. Analysis of the monetary value of the projected sales of the average delay of 3,6 months shows that the monetary value of sales is increased by +/- 9%. This is under the assumption that the market period is reduced by the months delayed, the average patent during sales is 9,4 years[5] and a yearly discount rate of 2% is applied from the start of the market period excluding the delay for both scenarios.

In order to generate societal impact as a result of the costs savings achieved by implementation of AMS in drug development, it is important that the costs savings not only translate to higher margins but also into the product price. The Fair Medicine model© has created a framework in which this mechanism is implemented and the costs savings will be translated in price reduction and thus, societal impact.

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Appendix

Appendix 1: assumptions

1. The delay that occurs as a result of an unexpected metabolite is between 12 and 24 months and the added costs are 200k USD and 500k USD respectively.
2. The distribution between the occurrence of the 12 and 24 month delay is equal.
3. Implementation of AMS in medicine development saves 750k in phase I because there is no separate trial needed for the human metabolite study.
4. Implementation of AMS results in a failure shift of 2% - 4% between phase III and phase II.
5. The patent protection during the products market period is 20 years[5] minus the development time of 10,6 years[2].