Phesi
Data-Driven Drug Development

Data Driven Drug Development: *Delivered*

Data-driven study design + High-performing sites + Accelerated activation = Smarter trials and faster cures

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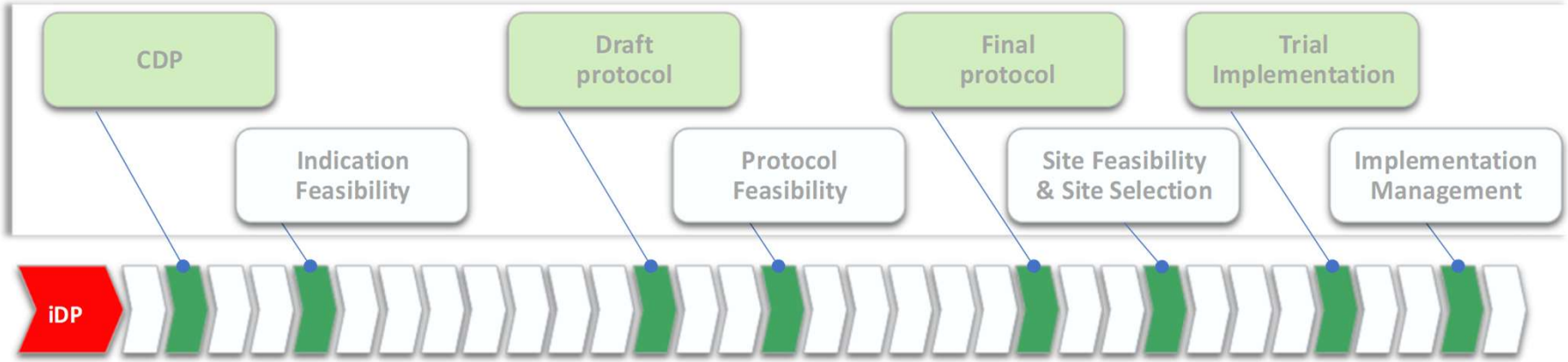
Data Driven Drug Development: Delivered

Reimagining Clinical Development: From Planning to Implementation



Use cases:

For the indication:

- Assess competition.
- Assess success rates of alternate trial designs (e.g. adaptive vs. traditional).
- Identify KOLs and high performing trialists.

For comparable protocols:

- Synthetic arm/ baseline patient characteristic profiling.
- In/exclusion criteria (including amendments) and impact on recruitment.
- High-performing countries, optimal number of sites and number of patients/ site.
- Recruitment scenarios.
- Suggest optimal site activation curve.

For final protocol:

- Short list of high-performing trialists/ sites.
- Suggested optimal site activation curve.
- Provide CRO insights and QA CRO site lists.
- Reduce non active/ non performing sites <10%.

For ongoing clinical trials:

- Monitor competition.
- Track site performance.
- Forecast enrolment rates and cycle time.
- Recommend operational adjustments- including crisis management.

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Features of the Integrated Phesi Clinical Trial Analytics Platform

Over 330,000 curated clinical trials

Over 80,000 dynamically updated data sources

4.2 million physicians and 600k Principal Investigators

Phesi platform established 12 years ago

69.7 million records in a single dimension to measure investigator site performance

11 patents filed and 2 new patents in process

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Case Study 1: Ulcerative Colitis Study Rescue

Trial was managed by a large CRO. Enrollment was severely behind plan. CRO suggested enrolling more sites in response to underperformance. Client wanted advice on whether this was the right course of action using a 'data led' approach.

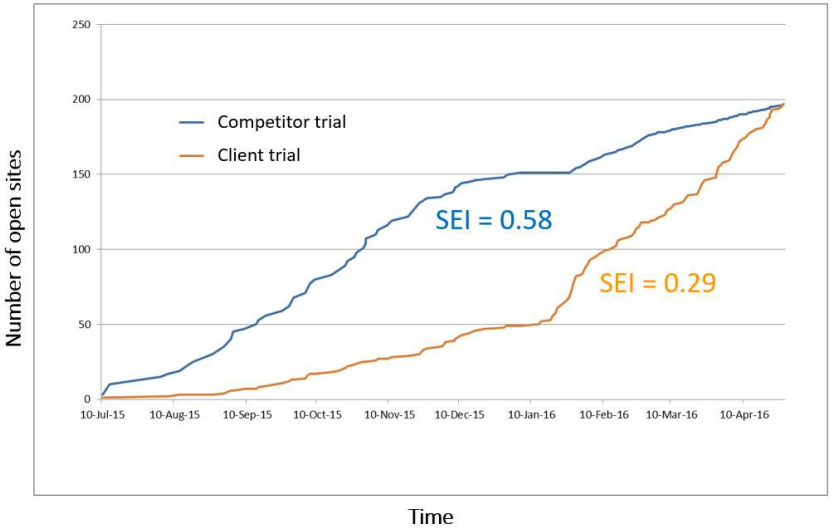
Phesi Analysis

Compared to similar clinical trials, trial sites had only enrolled about 50% of the patients. Enrollment was severely behind plan.

Using Phesi modelling, the optimal number of sites for the trial was 142 sites.

Mega CRO had already activated nearly 200 sites. This significant over usage of sites was hindering adequate support and focus on sites with the best potential to enroll.

Based on Phesi modelling of comparable studies, the original enrollment cycle time target was not felt to be realistic.



Site Effectiveness Index (SEI) is calculated by the area under the curve, and is a relative measure of available site capacity for the study that is being utilized

The site activation rate for client trial is low compared to other UC trials, contributing to lower enrolment.

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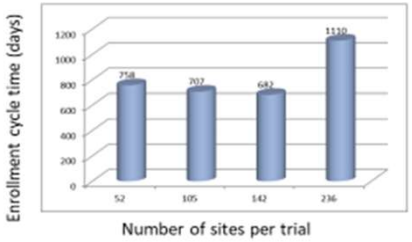
Case Study 1: Ulcerative Colitis Study Rescue

Interventions Recommended Based On Phesi Analysis

Actively monitor performance of already activated sites and immediately close sites that have not been contributing anything for more than 150 days (5 months).

Continue to close sites with pre-defined parameters until the number of sites reaches to 120-150.

While adding sites initially shortens enrollment cycle time, beyond a certain point this advantage erodes



The relationship between enrollment cycle time and site number follows a predictable, but not linear, pattern. Adding sites beyond a certain point negatively impacts performance.

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Case Study 1: Ulcerative Colitis Study Rescue

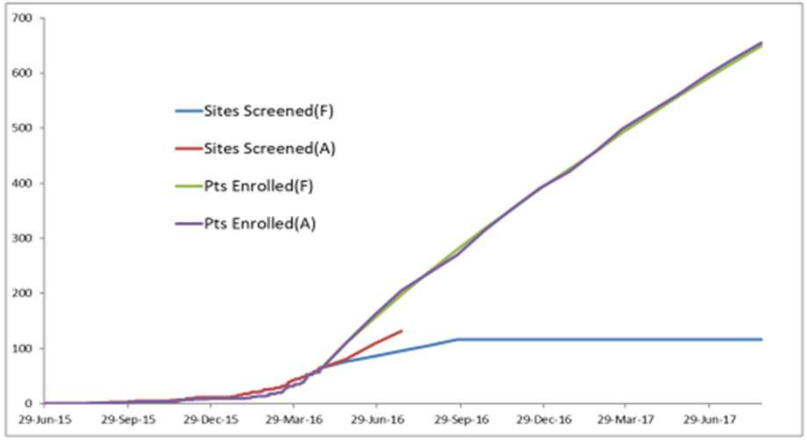
Outcome

Realistically we predicted that most of the enrolled patients would be contributed by 60+ sites that had already screened 1 or more patients.

It was reasonable to expect that 20 to 40 of the 120 activated sites would contribute patients.

We forecast to complete enrollment in 27 months, resulting in GSER of 0.12 pts per site per month, in line with historical data.

Phesi predicted time frame was "spot on". Study completed enrollment, as predicted, in October 2017.



Phesi was able to accurately forecast enrolment cycle time.

Conservatively, Phesi saved the client more than $3-5 million through reducing the number of sites needed (up to 50 sites).

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Synthesized Ulcerative Colitis Patient Profile

		"Synthesized" Baseline Patient Characteristics			Data from Real Trials for "Synthesis"	
Category	Variable	Mean	SD	Percentage of Patients (%)	Derived from #patients data	Derived from number of #trial arms
	Age (yrs), mean (SD)	36.1	12.5		11995	88
	Male			54%	25935	104
	Female			46%	21536	62
	Weight kg	74.6	16.4		3399	31
	BMI, mean, range	25.2	4.1		2109	17
	Duration of Ulcerative colitis (yrs)	8.0	7.4		16832	42
	Duration of Ulcerative colitis <1 year			23%	2513	11
	Duration of Ulcerative colitis >10 years			25%	2364	8
Mayo score	Mayo score	8.6	1.5		2481	32
Mayo score	Endoscopy sub score	2.5	0.5		1007	6
Mayo score	PGA sub score	1.2	0.7		2565	15
Mayo score	Rectal bleeding sub score	1.6	0.9		1259	9
Mayo score	Stool frequency sub score	2.5	0.7		1259	9
	Smoking, ever			22%	19154	70
	Smoking, never			75%	23755	31
Laboratories	C-reactive protein, mg/L	10.9	22.4		1845	18
Disease extent	Left-sided			47%	8514	63
Disease extent	Pancolitis			25%	6393	35
Disease extent	Proctitis			17%	1574	13
Flare frequency	Less than once a year			31%	2364	8
Flare frequency	More than once a month			4%	2210	7
Medications	Immunosuppressant			12%	1494	15
Medications	Azathioprine			42%	1634	15
Medications	Aminosalicylate			71%	4025	38
Medications	Corticosteroids			48%	3608	30
Medications	Mesalazine			63%	3198	31
Medications	Steroids			23%	3667	23

- Patient profile data can objectively guide protocol design and help to quantify the operational impacts from changes in inclusion/exclusion criteria.

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