Walking a Mile in the Shoes of the Decision Maker

- The importance of perspective
- Four examples
- Lessons Learned

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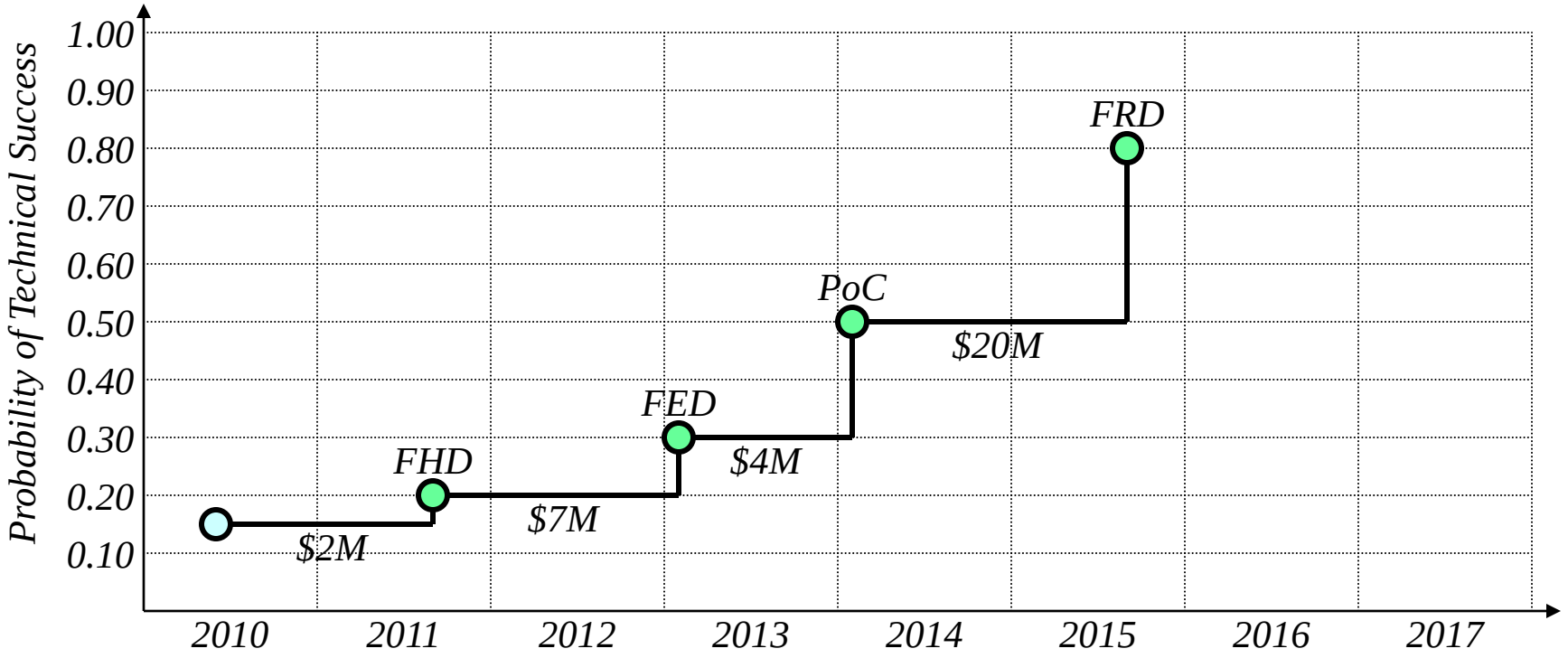
The Importance of Perspective

- As a teacher, how important is it to consider the perspective of the student if the goal is to impart understanding?
- As a consultant, how important is it to consider the perspective of the decision maker if the goal is to impart clarity of action?

Four Examples

- Efficiency Diagrams
- Productivity Trains
- Flow Scorecard
- Decision-Maker’s Bill of Rights

Efficiency Diagrams



Now to FHD ΔP = 0.05, $2M, 15 mos.

- Manufacture of clinical & toxicology material
- Preclinical toxicology

FHD to FED ΔP = 0.10, $7M, 17 mos.

- Phase 1 single-dose safety study
- Phase 1 multi-dose safety study
- 1-month rat toxicology

FED to PoC ΔP = 0.20, $4M, 12 mos.

- 3-month rat and monkey toxicology
- Phase 2a proof of concept study

FED to FRD ΔP = 0.30, $20M, 19 mos.

- Phase 2b dose-ranging study
- Drug-drug interaction studies
- 6-month rat and 1-year monkey toxicology

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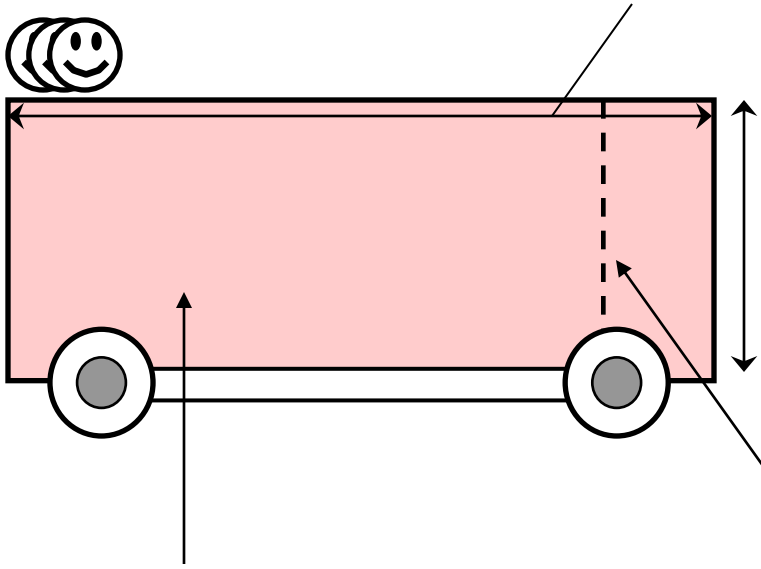
Productivity Trains

We used the metaphor of an engine pulling a train of boxcars to depict the productivity of the R&D pipeline. The boxcars represent projects in development, and the dimensions of the boxcar represent the key levers of project productivity. When the boxcars are compared to the target standard, it is easy to identify those projects that are making the most efficient use of R&D resources, as well as those projects that are "two-ticket" rides (or more).

The **number of faces** (patients) is a representation of the relative value of the project, given success

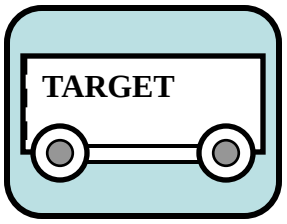
- 3 faces – high value
- 2 faces – medium value
- 1 face – low value
- 0 faces – yet to be valued.

The **length** of a boxcar is the number of days it is projected to be in this stage of development

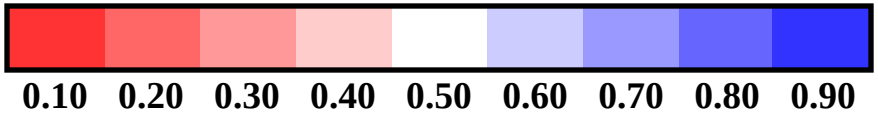


The **height** of a boxcar is the projected cost per day for this stage of development; therefore the boxcar's **area** is the total cost for this stage.

The target reference standard is depicted in the lower corner for each stage of development.

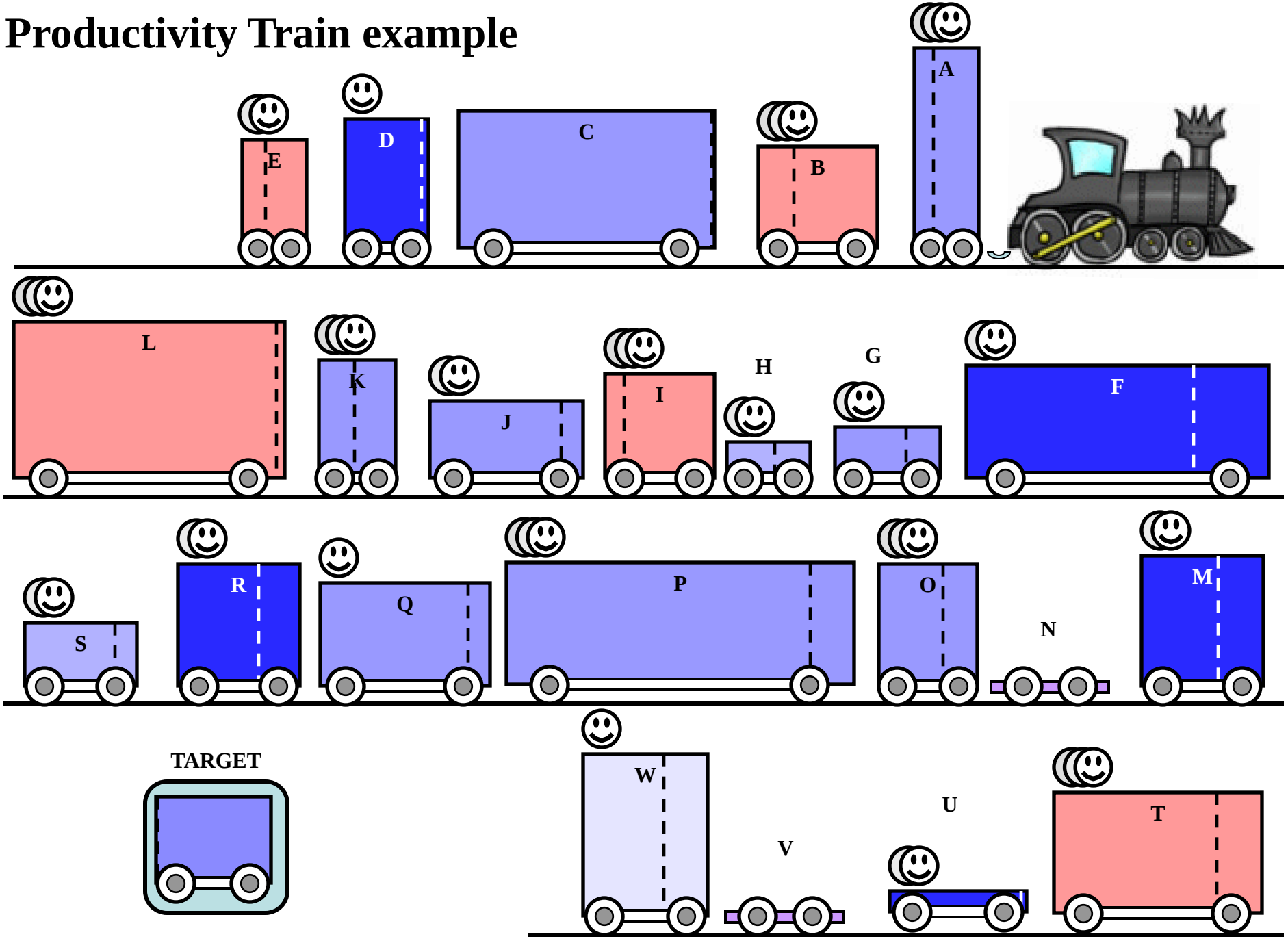


The **boxcar color** indicates its probability of technical success for this stage.



The **dotted line** indicates how much of the stage of development has been completed; the further to the right, the closer to completion.

Productivity Train example



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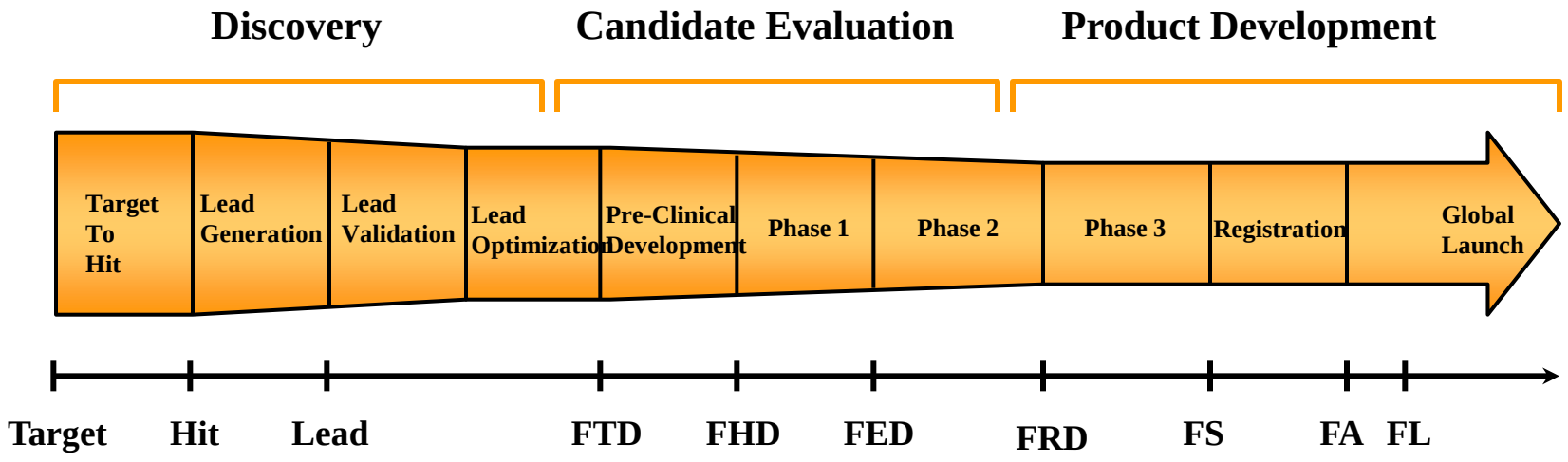
A Traditional Milestone Scorecard

Milestone	plan	YTD	% plan
Lead	32	8	25%
First Toxicology Dose	20	12	60%
First Human Dose	8	4	50%
First Efficacy Dose	6	3	50%
First Registration Dose	3	0	0%
First Submission	1	1	100%
First Approval	2	1	50%



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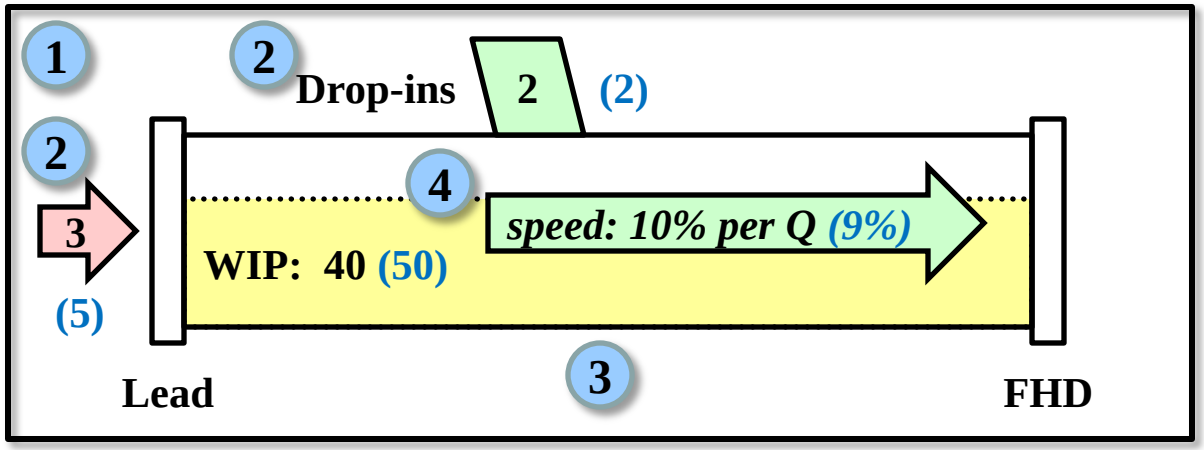
A **Pipeline Metaphor Map** is now used to provide clearer insight into the flow rates in the individual stages of development. For illustration purposes, the Lead to FHD portfolio for 1Q09 will be used in the following example.

1 Begin with a diagram of an empty pipe. The beginning of the pipe represents Lead, the end represents FHD. Molecules in this stage of development will be represented as liquid moving from one end of the pipe to the other.

2 Add in the two ways that projects can enter the pipe, either as a Lead or as a drop-in. There were 3 Leads and 2 drop-ins. The number of Leads was well short of the quarterly targets (in blue text), so the Lead arrow is colored red.



value	color
beat target	green
within 70% of target	yellow
lower than 70% of target	red

3 Add in the Lead to FHDWIP. There were 40 molecules in the portfolio at the end of 1Q09. It's short of the target of 50, so the water level is a bit low and the color of the water is yellow.

4 These 40 molecules were moving at an average speed of 10% per quarter. That is, it would take 10 quarters (2 ½ years) on average to go from Lead to FHD. This beats the goal of 9%, so the speed arrow is colored green.

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OK, so we have 40 molecules moving at a good average speed. But can they make it through to the next stage of development? That is where the P(FHD) comes in. On the Metaphor Map, this will be represented as the screen at the FHD end of the pipe. The coarser the screen, the higher the probability. The finer the screen, the lower the probability.

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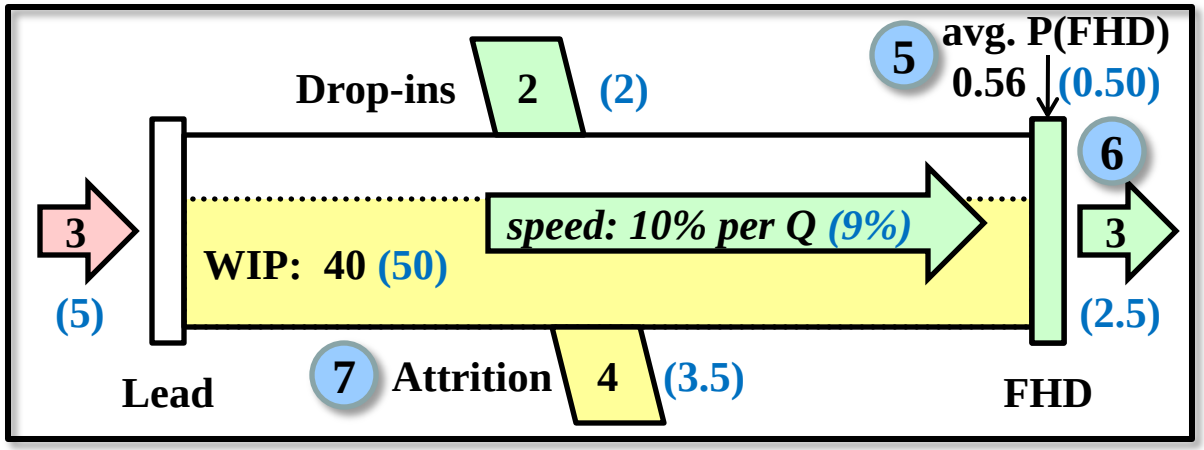
The average P(FHD) for these projects is 0.56. This also beats our goal of 0.50 so the screen, too, is colored green.

Let's recap. At the end of 1Q09, there were 40 molecules in the Lead to FHD portfolio, moving at an average speed of 10%, with an average throughput probability of 0.56. If we can keep this up, quarter after quarter, it will translate into an average flow rate of about 10.1 FHDs per year. But these are not the only contributors to 1Q09 flow.



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There's also the 3 molecules that achieved FHD and "graduated" to the next stage of development. Factoring in their speed and jump in probability, they contributed at a rate of 3.5 FHDs per year.

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Then there's the 4 NMEs that were terminated. This is less than 30% higher than the attrition expectation, so we color the drain yellow. Factoring in their position & drop in probability, this siphoned off flow at a rate of 1.5 FHDs/year.

Therefore, the overall flow rate for 1Q09 was 10.1 + 3.5 – 1.5 = **12.1 FHDs/year**.
That exceeds the flow target of **10 FHDs/year**.
We can now mark it down to quick projects with high throughput probability.

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R&D Flow Scorecard
Throughput Flow Rates

New Molecular Entities

	Target	Actual
Target to Lead	20.0 *Leads per year*	13.2
Lead to FHD	10.0 *FHDs per year*	12.1
FHD to FRD	2.5 *FRDs per year*	2.1
FRD to Launch	1.5 *Launches per year*	1.0

New Indications/Line Extensions

	Target	Actual
pre-FRD	3.5 *FRDs per year*	3.2
FRD to Launch	2.0 *Launches per year*	2.3

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The Decision Maker's Bill of Rights

1. You have the right to a Decision Frame that structures the decision in the context that is most relevant to your needs.
2. You have the right to Alternatives that allow you to make a selection among viable and distinct choices.
3. You have the right to be provided with Quality Information upon which to base your decision.
4. You have the right to understand the potential Consequences of each Alternative, based on your Decision Criteria.
5. You have the right to a Logical Analysis allowing you to draw thoughtful conclusions from the information.
6. You have the right to expect Clarity of Action for the choice you select.

Lessons Learned

- Does it make sense to you, or does it make sense to them?
- Does it make it easier for them to make their decisions?
- Revisit approaches as the organization changes
- Make it easy for the decision-maker to not only understand, but to explain to others
- “No assembly required”
- Can the metrics be “gamed”?