Clinical Trials Infrastructure

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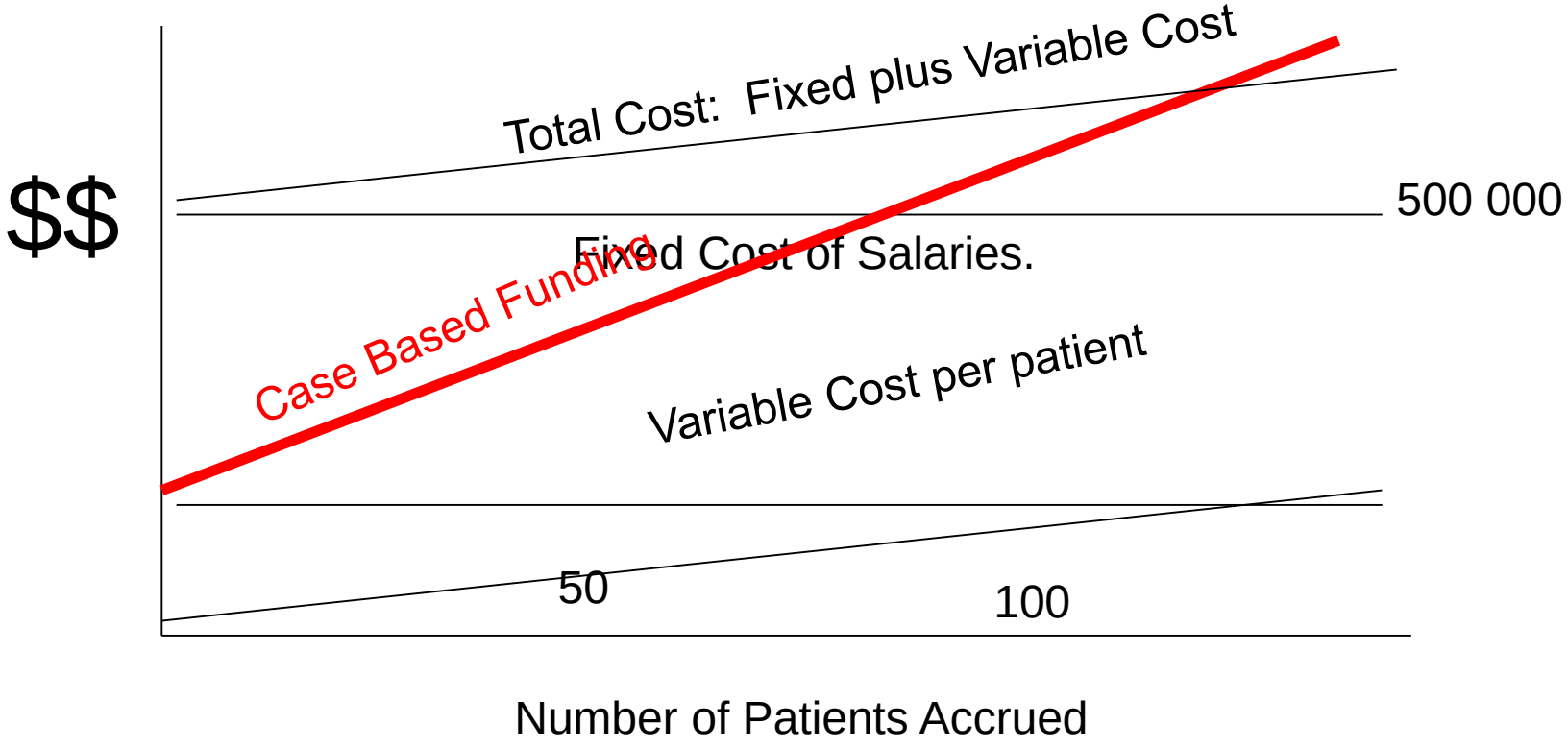
Goals

- Appreciate clinical trials complexity and improve efficiency

Simple

- Physicians can’t do clinical trials alone.
- Major cost is personnel – often a FIXED cost per year (good people want salary)
- Major revenue is per case funding
- Running a deficit is NOT an option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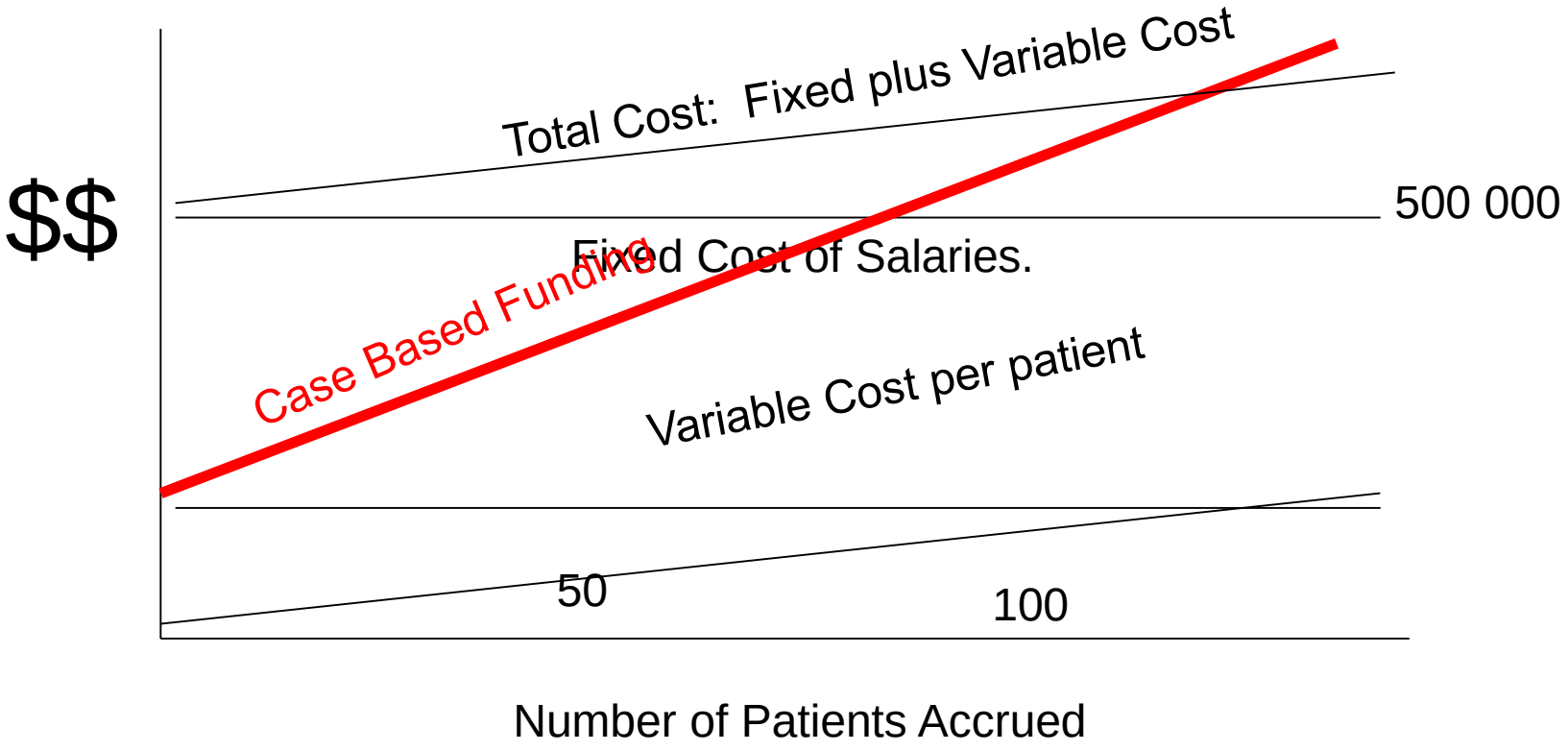
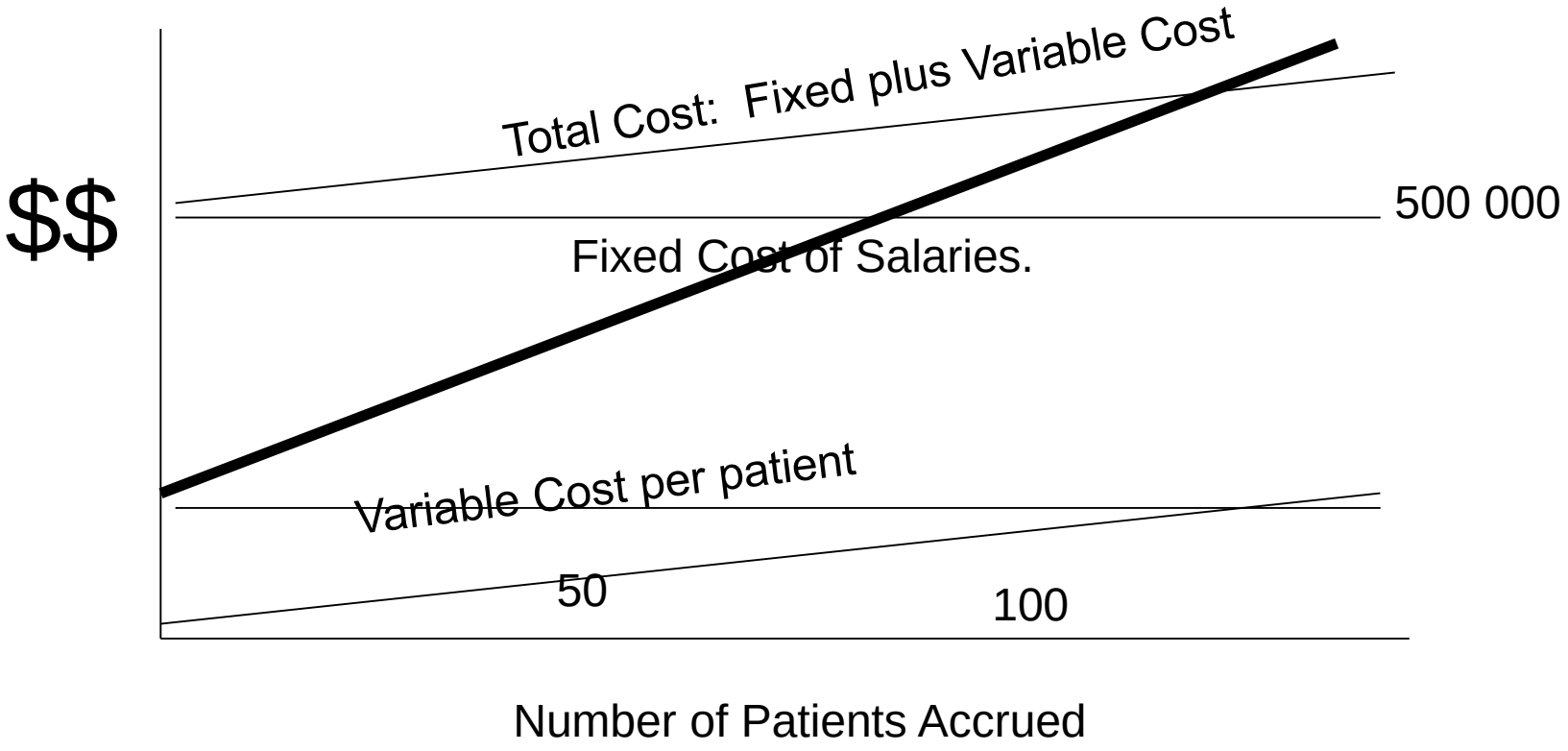
Total Cost: Fixed plus Variable Cost
500 000
Fixed Cost of Salaries.
Case Based Funding
Variable Cost per patient
50
100
Number of Patients Accrued

Case based funding depends on number enrolled. More important than high enrollment is accurate projection of enrollment.



The amount of variable costs will depend on the number of trials that need to be opened. 100 patients recruited with 20 trials is better than 100 patients with 40 trials .



Expected Revenue from Clinical Trial =

- # of patients accrued X Per Case Funding
- Therefore, increasing number accrued through:
  - Identification/education/recruitment strategies when open
  - Increasing time trial is open.
    - *A trial predicted to be open for 18 months and enroll 9 patients over that time period, that is delayed in opening for 6 months (at your centre), will have 33% less predicted revenue*

CRA's, CTA's, Managers, Trials Nurses etc.

- These personnel do most consenting, data entry, processing protocol amendments, REB submissions, asking for pathology blocks, ensuring slides are sent etc.
- The more complex the study, the more time is budgeted to these personnel
- The more a physician does (right), theoretically the lower cost for the trial (but who pays for it? Physician time isn't "free')

CRA's, CTA's, Managers, Trials Nurses etc.

- In general, to keep budgets appropriate, need to avoid OVERCAPACITY (i.e. people not working at income generating activity).
- Avoiding OVERCAPACITY, when workload is variable (i.e. certain times of year when new 'rush' of work occurs), means that sometimes your study needs to wait.
- i.e. if it can open tomorrow, then was your clinical trials unit really running at capacity?

Work to streamline trials (reduce costs)

- ?Oral consent documented by physician when comparing standards of care
- ?database follow-up/health system EMR follow-up
- CCCTN and N2N strategies
- ?Ethics central

Work to make trials more complex:

- Central Review of imaging and accreditation
- Multiple Amendments that require reconsenting
- Multiple ‘training’ for EDC, ethics etc.
- More complex chemo order entry systems, pharmacy time etc.
- Budget crunch, increased financial reporting
- CCO STFM model (or other provincial models)
- CRO’s with ‘this is what we require’

“You need a mix of industry and academic studies”

No, you need sound financials either way

Beware Hidden Costs, CRO’s that are difficult to work with, per case funding vs. upfront piecemeal etc.

Industry studies should not be Subsidizing academic studies or vice-versa.

Dilts et al: 2006 JCO: Invisible Barriers to clinical trials, the impact of structural, infrastructural, and procedural barriers…

- Over 110 steps required, 50% non-value added
- 6 months = median time to activation

Next steps:

- Play and Discussion: 20 minutes
- Share learned experiences; 10 minutes