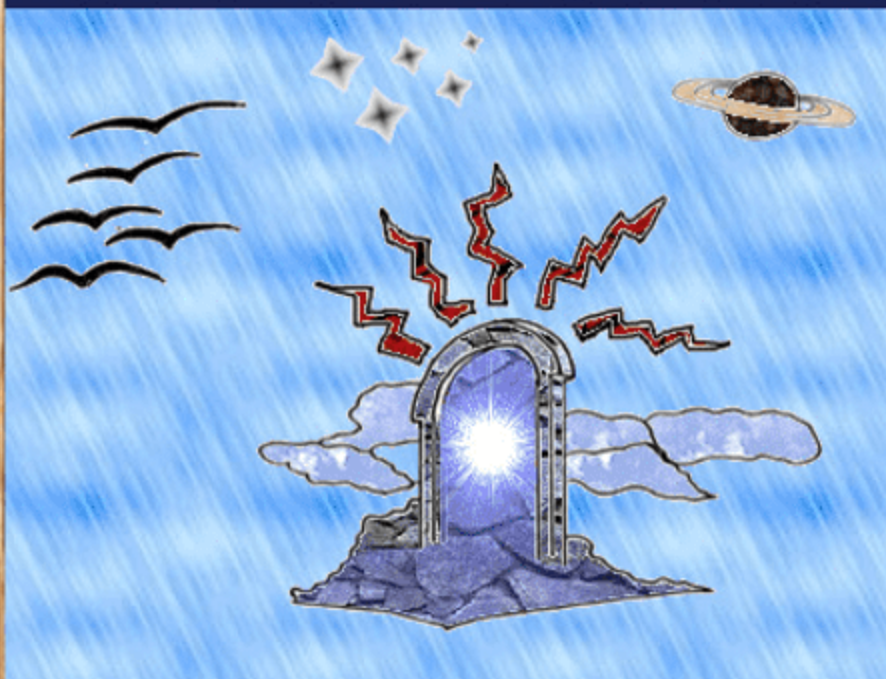


Unconventional Wisdom Series

Oncology Data Not Enough



Jean Patrick Tsang, PhD & MBA (INSEAD)

Bayser Consulting
4709 Golf Rd, Suite 803, Skokie, IL - 60076
Tel: (847) 920-1000 Email: bayer@bayser.com
Web: www.bayer.com

If you manage a brand or are tasked with answering questions in the Oncology space, you already know this: Data is a huge problem. In a nutshell, there is not enough data and the data is not enough. What to do?

Not enough data - In some cases, the capture rate can be as low as single digit. Capturing sales of our product is usually not the problem. If our product has REMS status, the capture rate is perfect, 100%. It's the competitive activity that is the issue. That's the case when distribution goes through SP's and data contracts preclude the SP's from sharing competitive prescription activity.

Data not enough - Indeed, the data does not report key clinical information on the patients. It may say breast cancer, but does not say metastatic (by the way, there are no ICD-9 codes to indicate metastatic) let alone the ER/PR or HER2 status of the patient. What's more, the data will not indicate stage and/or line. While lab tests will be captured and lab results about LDL, HDL, TG, and A1c may be captured, lab values for BRAF, KRAS, EGFR, and the like are almost never reported. Hospitalizations and interventions taking place outside of the physician office (e.g., transfusion) will rarely be reported reliably. Another challenge is drug combinations. As we know, orals are reported on NCPDP claims and IV's on CMS-1500 claims. The problem is that the capture rates are different. As an example, in a market where for each oral (one NCPDP claim), there is one IV (one CMS-1500 Claim with a J-code), for 2 NCPDP claims that appear in the data, one CMS-1500 claim is left out.

How does the industry operate? By relying on Primary Research primarily. Really. Indeed, a few hundred oncologists are surveyed on a continuous basis and their answers are tabulated and packaged as monthly deliverables. The good thing is the data is timely and has the requisite clinical richness. The bad thing is N is very small, and it is very difficult to tell apart noise from signal. When the data reports a sudden swing in market share, we cannot say if it's for real or simply the doing of a few oncologists on the panel. That's why monthly market shares are reported as Rolling n months. By taking the average of the last n months, swings are dampened in the hopes of shielding us from noise.

Can we do any better? The answer is a resounding yes. Here are a few things we can do.

1. Enhance the findings of the Primary Research with findings of large-N databases (e.g., PLD, EMR, etc.). This will increase the signal-to-noise ratio. The usual objection is this is not feasible because the time frames of the data assets are different. Do not be put off by this distraction. The workaround consists of bridging the databases over an older data window, inferring "exchange rates" between the databases, and carrying out the adjustments forward, on the more recent data.

2. Get more data. The Payer manages the checkbook and as such will be privy to virtually all healthcare interactions of the patient, regardless of the fact that the claim is paid or rejected. Get data from payers (e.g., Optum, Humana, PharMetrics Plus, Truven, etc.) if you really need to get a better read on the competition. One of the challenges with this approach, apart from the fact that it is expensive, is that the id of the physician is encrypted, but that should not be a showstopper. Another avenue consists of enhancing our data with freely available databases. There are several of them: Medicare Parts B/D, Referrals data, Sunshine Act data, and the like. The issue here is the CMS data may be dated (a real concern if we are looking at new launches) and will not say much about younger patients.

3. Get clinically richer data. The industry is already moving in this direction. Indeed, PLD data vendors are offering merged data (the data is merged with lab results, EMR's, and registries). We refer to this as fourth component data. That's because PLD currently comprises 3 sources, namely, NCPDP, CMS-1500, and UB-04. One of the issues here is significant thinning of the sample size. If an EMR or registry has N patients and this data is merged with data from a payer that reimburses say 10% of the US population, then the database will contain at most N/10 patients, which in some cases may be a non-starter (orphan diseases).

4. Enhance PLD data using rules. In a nutshell, the rules look at the drugs, diagnoses, and procedures of the patient and infer the stage/line and subtype of the cancer. The good thing about this approach is that there is no thinning of the patient universe as in the case of 4th component data. The bad thing is we need to come up with these rules and establish their clinical soundness. One of the research avenues we are conducting consists of deploying probabilistic cancer stage and subtype maps which, if successful, would greatly decrease the need for these rules.

5. Combine databases. Yet another approach consists of combining databases. Being clever may not be the most challenging part. Indeed, one needs to make sure that the combined database still fails the HIPAA test (ability to identify a patient). By the way, if data vendors frown upon data merging, it's because they are concerned you may pass the HIPAA test.

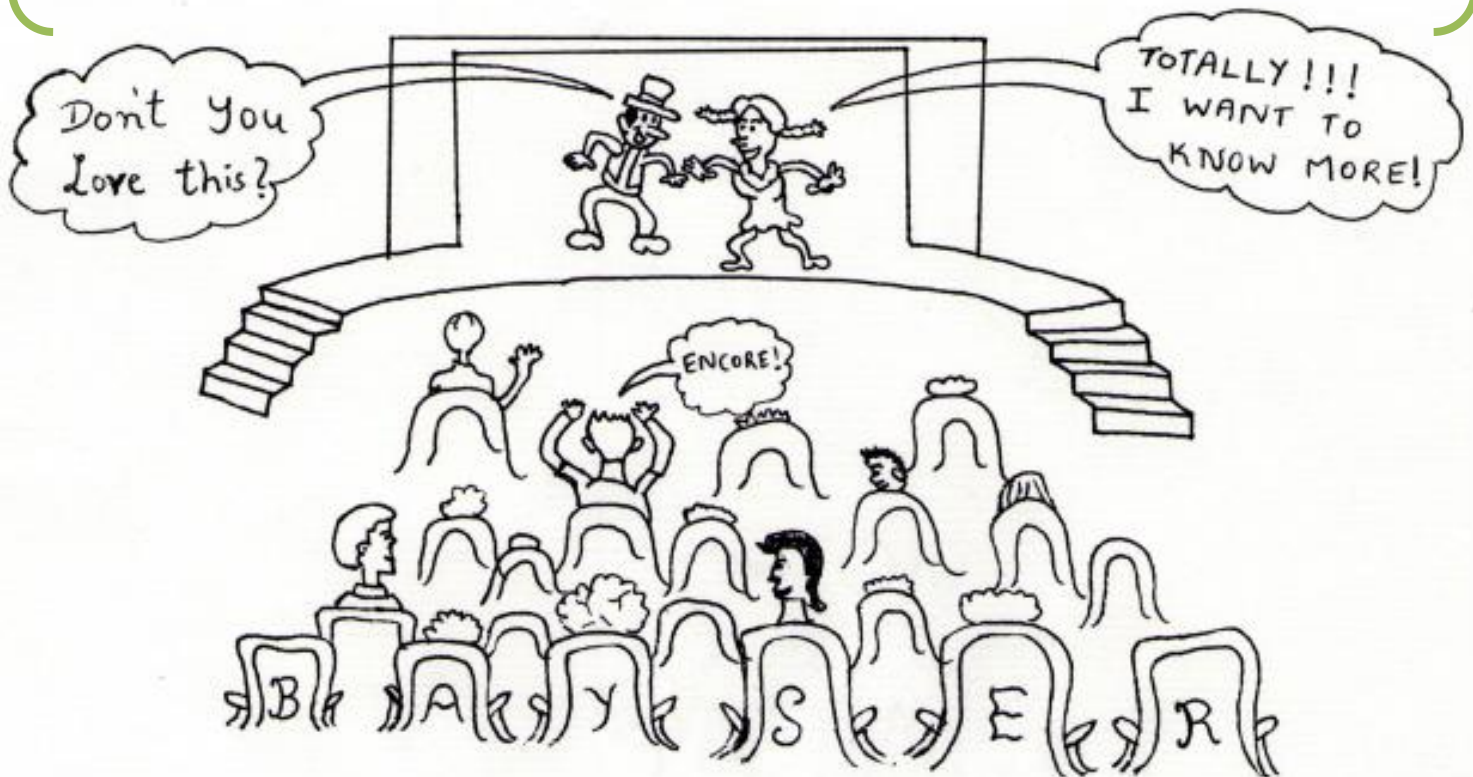


JP Tsang, PhD & MBA (INSEAD)

Founder & President

Jean-Patrick Tsang is the Founder and President of Bayser, a Chicago-based consulting firm dedicated to pharmaceuticals sales and marketing. JP has worked on 250+ projects to date including ROI optimization, data strategy, and study design to mention just these. JP publishes and gives talks on a regular basis and runs one-day classes on various subjects related to data and analysis.

In a previous life, JP deployed Artificial Intelligence to automate the design of payloads for satellites and was the adviser of two PhD Students. JP holds a Ph.D. in Artificial Intelligence from Grenoble University and an MBA from INSEAD in France. He was also the Recipient of the PMSA Lifetime Achievement Award in 2015. He can be reached at (847) 920-1000 or bayer@bayer.com.



BAYER

**4709 Golf Rd, Suite 803,
Skokie, IL 60076**

**(847) 920 - 1000
bayer@bayer.com**