Title
Adverse Drug Reaction Case Safety Practices in Large Biopharmaceutical Organizations from 2007 to 2017: An Industry Survey

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Supplement 1: Structured Interview Guide

1. What will reduce cost of PV operations moving forward?

Potential Cost Driver: Change in Case Volumes Over Time
2. [show data from comparing number of individual case safety reports across time]: What is driving growth in case volume?
   a. Of those drivers, which are artifacts of the 2012 EMA/MHRA legislation (GPV)
   b. Which are sustaining (i.e. not due to the 2012 legislation)?

Potential Cost Driver: Regulatory
3. What are the biggest challenges across regulatory jurisdictions?
4. Navitas Life Sciences’s analysis found that the following countries are have challenging regulatory environments [Saudi, Egypt, Russia, Other Arab Countries, Kazakhstan, LatAm]. What makes these regulatory jurisdictions challenging to navigate?
5. What statutory or regulatory remedies, or policy improvements, are needed in PV operations with regard to operational efficiencies?
6. What are the two or three biggest challenges in regulatory compliance?
7. Focusing a moment on Europe, what will happen when the 2012 legislation that was passed in the EU/MHRA changes? (they are reporting that this will occur)

Potential Cost Driver: Labor
8. What are the most labor-intensive activities in your PV operation? Tell us about three of them. Also, who is doing the work for these labor-intensive activities?
9. Of the activities you just mentioned, what are your thoughts on the value brought to the business by each activity?
10. How have your Pharmacovigilance (drug safety) teams evolved in terms of:
   a. composition,
   b. skill sets, and
   c. geographic distributions over the last three years?
11. We talked briefly about some of the labor-intensive activities outsourced. Looking at outsourcing overall, what has your company found to be the biggest benefits?
12. What have been the biggest challenges?

Potential Cost Driver: Technology
13. Which of the following technologies have you found most helpful in improving your PV Operations? Examples include:
   a. Optical Character Recognition (OCR) and data transcription services
   b. Auto encoding / MedDRA coding
   c. Other intake services
   d. Speech to Text Technologies
   e. Auto Translation Technologies
   f. Machine/Deep Learning Applications
14. For the benefit gained, have they been worth the investment?
15. How do the number of data sources used in PV today compare to the number of data sources referenced ten years ago? Has this change increased the cost/complexity of capturing case data? How so?
16. Do you think artificial intelligence (AI) and/or Cognitive computing could decrease the cost/complexity of capturing case data?
   a. If no, why not?
   b. If yes, why, and where in the process?

Closing Thoughts
17. Traditionally PV Operations has been viewed as a cost center. Does your organization have any strategies on how to change this view to more of a value-generating center?