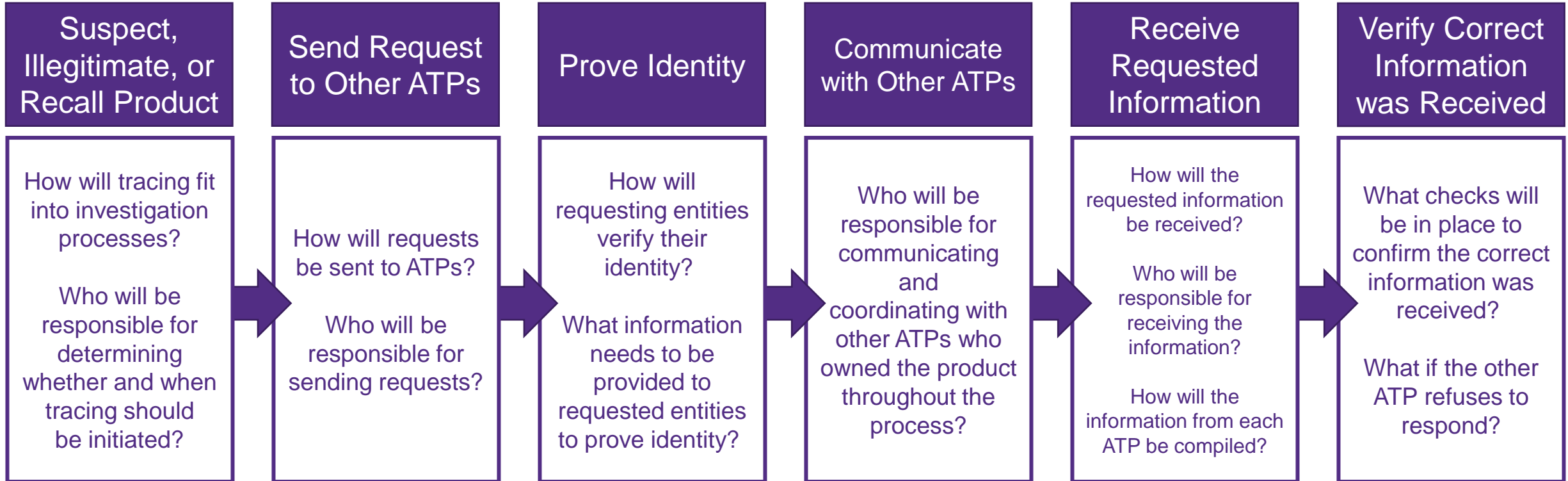


# Considerations in Designing Tracing Processes

This document identifies the various steps involved in the process of initiating and responding to tracing requests under Sec. 582(g)(1) of the FD&C Act. It is intended to aid trading partners in developing their internal standard operating procedures (SOPs) by identifying key questions that should be considered in the development of those SOPs. This is not intended to define an individual trading partner's process, nor is it necessarily exhaustive in identifying *every* component of an SOP. Rather, it is an informational guide to help trading partners identify some of the significant components for consideration.

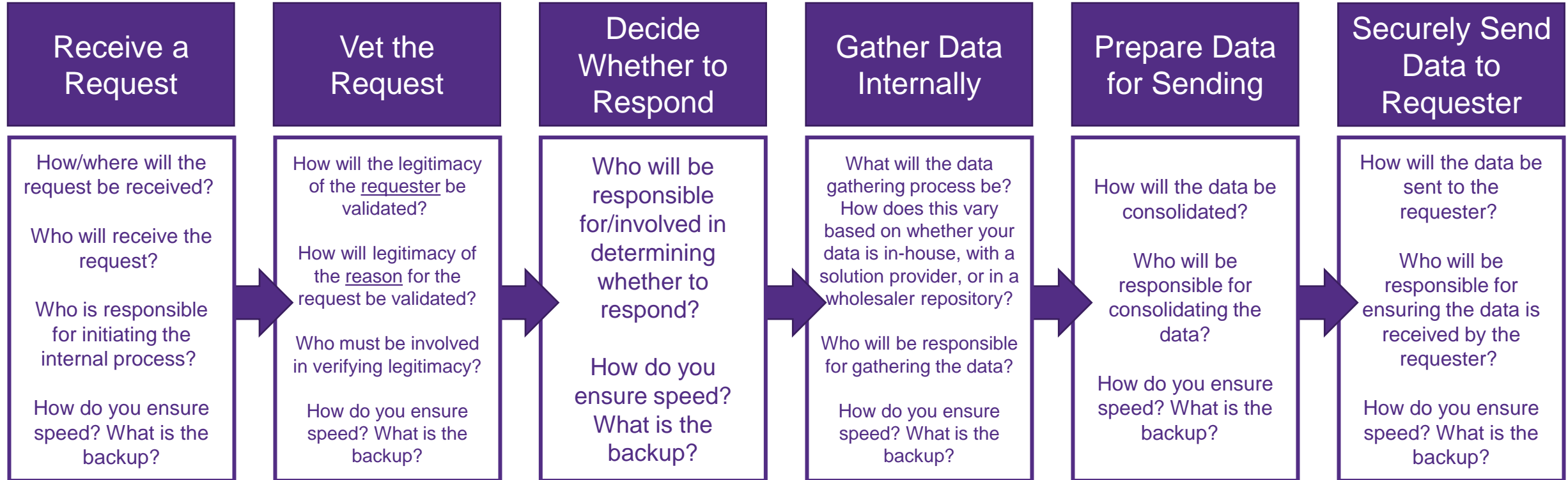
**This document is for educational purposes only, does not represent a formal PDG position, and is not legal advice. It has not been ratified by the PDG membership.**

# Initiating a Tracing Request



To what extent do internal business, legal compliance, and data security teams need to be involved in each step?

# Responding to a Tracing Request



To what extent do internal business, legal compliance, and data security teams need to be involved in each step?