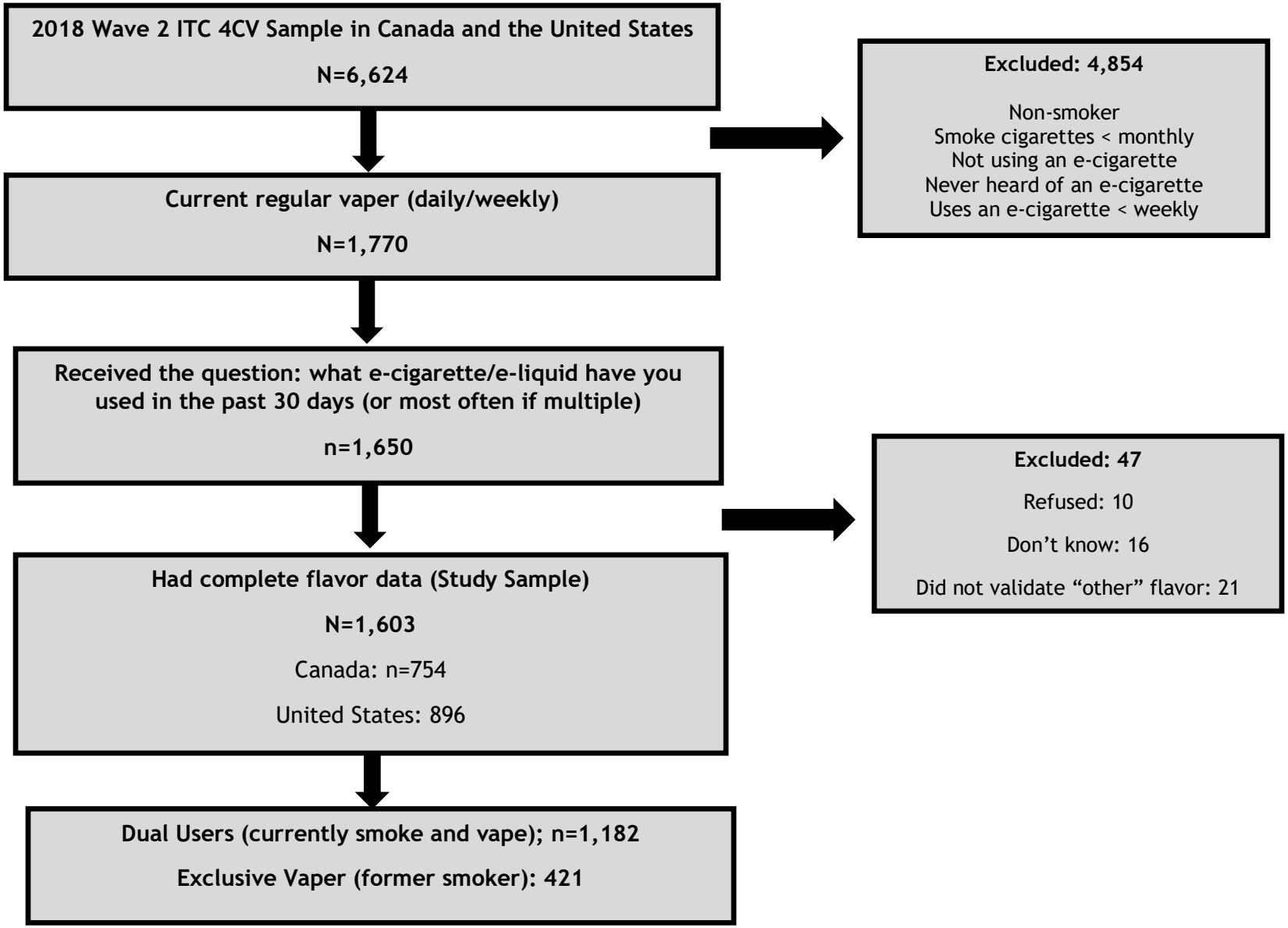Supplemental Figure 1. Study Flow Diagram