

**Public Comment:**

**Col. Dan Harms**

**Translation of Academic RUO to Clinical Lab**

Need to ensure that “translation” of a RUO to clinical lab does not circumvent/unnecessarily degrade IVD device clearance/approval process under the guise of a LDT. The FDA’s process provides a national standard for assessing performance of an IVD device. This process should not be unnecessarily undermined for the sake of expediency.