1. **Purpose of Contact: Discussion of REC 312420**
2. **Teleconference held 7th Aug 2019, 1:30 pm IST**

## FDA ATTENDEES

1. George Martin, MA, MBA, MSW,LSW, Clinical Supervisor, (DIRM) – (DH)
2. William Walker, Junior Program Management Officer, DIRM
3. Muhammed Ali, MD-PhD, Clinical Team Leader, (DIRM)
4. Rocky Balboa, MD, Clinical Reviewer (DIRM)

## SPONSOR (ATOS)ATTENDEES

1. Ronald Wesley, PhD, Senior Executive Director, Regulatory Affairs (JB)
2. Wesley So ,Junior Associate Director, Regulatory Affairs, CMC
3. Ding Liren, PhD, Sr. Vice President, Chemical Development (JE)
4. Anish Giri, PhD, Sr. Executive Manager, CMC - Nuclear Medicine
5. Charlie Chaplin, Junior Director, Ethics
6. Leonard Kingsley., President, Clinical Development

1. Call started at 1:30 pm IST with introductions. Call ended at 1:07 pm GST.

William Walker: FDA acknowledges development program, that Invivo is the organization who developed the process and methods for the diagnostic, however FDA needs to see executed validation batches (3) from diagnostic at the radio pharmacy to verify Invivo process to confirm the applicability of specifications. There is insufficient information to assess the IND. For example, they expect to see sterility assurance. These are considered to be quality issues and safety issues. Without seeing these data FDA cannot recommend that it is safe to proceed with this IND.

This is consistent with last telecon, Sponsor (ATOS) is currently generating data. Which will be provided as response to this clinical hold. The estimated timeframe for the response is mid-February (2023), perhaps the second half/third week of February. Sponsor (ATOS) commits to update FDA as we generate the information.

ACTION: Sponsor (ATOS) will review the letter and contact them (FDA) if necessary.