MANA RBM
DELIVERING RISK BASED MONITORING SOLUTIONS

WI #:	TITLE	VERSION DATE
WI-PM-3010	Certification for the Use of Electronic Signatures	21-DEC-2017
		VERSION #
		V1.0

1. PURPOSE

These instructions are to be followed to certify to the FDA that MANA RBM ensures that electronic signatures meet FDA requirements and that the signatures are considered trustworthy, reliable, and generally equivalent to handwritten signatures executed on paper.

2. APPLICABLE ROLES

Project Manager

3. PROCESS

Step	Responsible Role	Activities	Timing
1	PM or designee	• Confirm if sponsor has submitted the Letter of Certification to the FDA. If the letter was sent, obtain a copy and file in the eTMF. • If letter has not been submitted determine which party (MANA RBM, Sponsor, etc.) will be responsible for submitting the letter to the FDA.	Upon execution of the study contract, prior to the use of eSignatures for study documents.
2	PM or designee	If MANA RBM is responsible for sending the letter: • Prepare and submit the Letter of Certification for digital signatures to the FDA. Use template TPL-PM-3007: Letter of Certification (letter to FDA) • The letter must be submitted (preferably on company letterhead) and signed with a traditional handwritten signature. • File a copy of the letter in the eTMF.	Prior to the use of any eSignature

4. ABBREVIATION LIST

ABBREVIATION	DEFINITION
eTMF	Electronic Trial Master File
FDA	US Food and Drug Administration
PM	Project Management
TPL	Template
WI	Work Instructions