



## MTN-035 Operational Guidance #2

### MTN-035 SMS PD Reporting

The purpose of this Operational Guidance is to define Short Message Service (SMS)-related protocol deviation (PD) reporting requirements in MTN-035/DESIRE. Study sites should adhere to these criteria upon receipt of IRB/EC approval for Letter of Amendment (LoA) #01, dated 06JAN2020. Prior to receipt of IRB/EC approval, study sites should continue to report all SMS-related PDs.


In the following scenarios, report PDs as indicated:

- SMS is not sent to participant (e.g., due to system-wide technical issue/outage, either at the participant or network level) – **Do not report PD**
- SMS is sent to but not received by participant (e.g., due to malfunction of participant's mobile phone device or a phone number change, etc.) – **Contact Management Team for guidance**
- SMS is received by but not responded to by participant (e.g., due to participant decline) – **Report PD**
- SMS is sent prematurely (e.g., weekly SMS is sent prior to participant's Product Switch Visit following a change in their follow-up schedule, and system is not updated to delay SMS distribution to match new follow-up schedule) – **Report PD**

As stated in LoA #01, study sites may forego SMS procedures for collection of adherence and acceptability data when the SMS system malfunctions or forego them entirely if lacking the necessary infrastructure to reliably use SMS for data collection. In those instances, data that would otherwise be collected via SMS will be collected during the in-depth interviews (IDI) taking place at the product use end visits (PUEV). Following IRB/EC approval of LoA #01, such instances do not constitute PDs.

Questions on this Operational Guidance or any SMS-related PDs should be directed to the MTN-035 Management Team.

This Operational Guidance document must be printed and filed with regulatory documentation.

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Sherri Johnson, Sr. Clinical Research Manager, FHI 360


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## Witness Events

Signature

Timestamp

## Notary Events

Signature

Timestamp

## Envelope Summary Events

Status

Timestamps

Envelope Sent	Hashed/Encrypted	1/27/2020 10:34:20 AM
Certified Delivered	Security Checked	1/27/2020 10:40:11 AM
Signing Complete	Security Checked	1/27/2020 10:40:47 AM
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