

# Suggested Format For IDE Progress Report (Text Only)

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

## Suggested Format For IDE Progress Report

### 1. Basic Elements

- IDE Number
- Device name and indication(s) for use
- Sponsor's name, address, phone number, and fax
- Contact person

### 2. Study Progress

(Data from beginning of the study should be reported, unless otherwise indicated.)

- Brief summary of the study progress in relation to the investigational plan
- Number of investigators/investigational sites (attach list of investigators)
- Number of subjects enrolled (by indication or model)
- Number of devices shipped
- Brief summary of results
- Summary of anticipated and unanticipated adverse effects
- Description of any deviations from the investigational plan by investigators (since last progress report)

### 3. Risk Analysis

- Summary of any new adverse information (since the last progress report) that may affect the risk analysis; this includes preclinical data, animal studies, foreign data, clinical studies, etc.
- Reprints of any articles published from data collected from this study

- New risk analysis, if necessary, based on new information and on study progress

#### 4. Other Changes

- Summary of any changes in manufacturing practices and quality control (including changes not reported in a supplemental application)
- Summary of all changes in the investigational plan not required to be submitted in a supplemental application

#### 5. Future Plans

- Progress toward product approval, with projected date of PMA or 510(k) submission
- Any plans to change the investigation, e.g., to expand the study size or indications, to discontinue portions of the investigation or to change manufacturing practices (NOTE: Actual proposals for these changes should be made in a separate supplemental application).

**More in Guidance Documents (Medical Devices and Radiation-Emitting Products)**  
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)**

**Cross-Center Final Guidance**  
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)**

**Office of Compliance Final Guidance**  
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)**

**Office of the Center Director Final Guidance**  
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)**

**Office of Communication and Education Final Guidance**  
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)**

**Office of Device Evaluation Final Guidance 2010 - 2016**  
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)**

**Office of Device Evaluation Final Guidance 1998 - 2009**  
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)**

**Office of Device Evaluation Final Guidance 1976 - 1997**  
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)**

**Office of In Vitro Diagnostics and Radiological Health Final Guidance**  
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)**

**Office of Surveillance and Biometrics Final Guidance****(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)****Office of Science and Engineering Laboratories Final Guidance****(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)****Draft Guidance****(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)****Radiation-Emitting Products Guidance****(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)****Withdrawn Guidance****(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)**