

If this is the **Final Report** for a **Clinical Trial**, please also complete the second section of this template.

Date: JDRF File Number:

Principal Investigator:

Institution Name:

Phone:

E-mail:

Title:

JDRF SCIENTIFIC PROGRESS REPORT

Please indicate which type of report this is:

Annual Report ___ Quarterly Report ___ Interim (Semi-Annual)___ Final Report_____

Please indicate which period the report describes:

Year 1___Year 2___Year 3___ Year 4___ Year 5___

Quarter 1___Quarter 2___Quarter 3___Quarter 4___ Interim (Semi-Annual)___

Goals for this reporting period:

Please list the specific aims or milestones targeted during this reporting period and indicate their status (ie. completed, in progress, delayed)

Accomplishments in the past reporting period (bullet points):

Significant Progress towards Milestones in the past reporting period. If milestones are delayed list revised projected completion dates (include summary of data in tabular or graphic form):

Goals for next reporting period:

Bottlenecks/Requests for Possible JDRF Facilitation:

Administrative issues that may impact progress, renewal, etc.



Future plans (Final Report only):

Please include a brief description of any plans to continue this research including future goals and future funding plans.

FINAL PROGRESS REPORTS ONLY

[This section applicable for Clinical Trials only]

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If the research study is a Clinical trial [as defined by NIH definition of Clinical trial-Oct2014], JDRF requires submission of the trial results in ICH-E3 summary format below: For more guidance on structure, content and format, please refer ICH-E3 guidelines-link below:

<https://www.ich.org/page/efficacy-guidelines>

SYNOPSIS

Title of Study			
Investigator(s)			
Study centre(s)			
Publication (reference)			
Study period	From: To:	Phase of development	Phase
Objectives	<u>Primary Objective</u> <u>Secondary Objective</u>		
Methodology			

Number of patients	Planned: Analysed:
Diagnosis and main criteria for inclusion	
Test product, dose and mode of administration, batch number	
Reference therapy, dose and mode of administration, batch number	
Duration of treatment	
Criteria for evaluation	Efficacy: Safety :
Statistical methods	

<p><u>SUMMARY CONCLUSIONS</u></p> <p>EFFICACY RESULTS</p> <p>SAFETY RESULTS</p> <p>CONCLUSION</p>



Please include any data tables relevant to the trial regarding disposition of patients, major protocol deviations and demographics of the study patients.