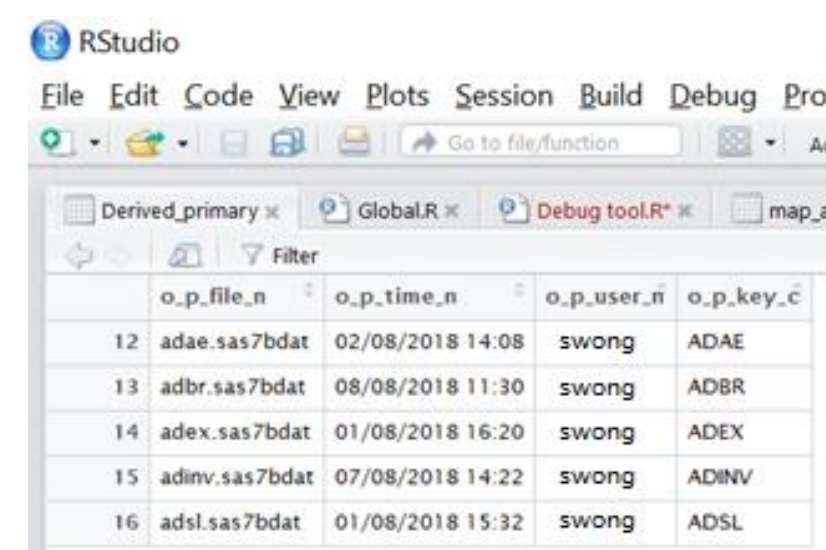



Automated 21 CFR 11 Compliant Signature

Despite its comprehensive functionality, ID-Imagine is undergoing continuous development to enhance multi-user support, security, and IT integration. It embodies the fusion of biostatistics practices and software innovation, underscoring our commitment to leading edge methodologies and operational excellence in biostatistics.

Date, File name,
User information





IDDI

PASSION. SCIENCE. EXPERIENCE.

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Page 11 of 11

Check the date of the raw data sets Compare with the database extract date mentioned in the footer of the tables	Done by on
---	-----------------

Biostatistician(s)/programmer(s) who performed the validation :

Standardized Output Formatting

Th3a_gpposser - my_gprovalist
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Page 1 of 82



On behalf of
My_gposser

PROTOCOL NO: 888888
Open label, multicenter phase I study

04 Apr 2024

Results

Th3a_gpposser - my_gprovalist
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Page 2 of 82

TABLE OF CONTENTS

Table 14.01.07.01: Baseline Disease characteristics.....	3
Table 14.01.08.01: Previous vs. Treatments.....	17
Table 14.01.10.01: pCR Performance Status.....	27
Figure 14.02.06.01.01: Graph of Pruritus VAS - median score over time overall and by type of best global response (Q/P/N, SD or PG).....	29
Figure 14.02.06.02.01: Graph of Pruritus VAS for patients with CR or PG as best overall response - baseline vs. best change.....	30
Figure 14.02.06.03.01: Graph of Pruritus VAS for patients with SD as best overall response - baseline vs. best change.....	31
Figure 14.02.06.04.01: Graph of Pruritus VAS for patients with PD as best overall response - baseline vs. best change.....	32
Table 14.02.08.01.01: Time to adjuvant response - Summary Results.....	33
Figure 14.02.12.01.01: Graph of relative change of global mCRNA score over time by patient and by BCR.....	39
Figure 14.02.15.01.01: Graph of relative change of neoplastic cells over time by patient and by BCR.....	40
Table 14.03.04.01.01: TSS4 by SSC, PE, and severity regardless of the dose level.....	41

Th3a_gpposser - my_gprovalist
All results
Confidential
Page 3 of 82

Table 14.0x.07.0x: Baseline Disease characteristics

Previous: my_gposser
Safety Population - Not x: Overall population (per x=0)

	ALL	0/0x1 mg/kg	0/0x2 mg/kg	0/0x3 mg/kg	0/0x4 mg/kg	0/0x5 mg/kg	0/0x6 mg/kg
	N=64	N=24	N=24	N=24	N=24	N=24	N=24
Number of patients							
Time from initial diagnosis of CRCL and date of first administration of vvx3 (months)							
x	44	x	x	x	3	3	
Mean	17.5	16.0	16.9	16.5	16.0	15.5	16.9
SD	09.96				34.05	34.06	
Median	16.7	16.0	16.0	16.5	16.0	15.5	16.9
Qx.01	15.0	15.0	16.0	16.0	16.0	15.5	16.9
Max	31.0	16.0	16.0	16.0	16.0	15.5	16.9
Time from last disease progression to first injection (months)							
x	44	x	x	x	3	3	
Mean	16.5	16.0	16.0	16.5	16.0	15.5	16.9
SD	09.96				34.05	34.06	
Median	16.5	16.0	16.0	16.5	16.0	15.5	16.9
Qx.01	15.0	15.0	16.0	16.0	16.0	15.5	16.9
Max	31.0	16.0	16.0	16.0	16.0	15.5	16.9

Th3a_gpposser - my_gprovalist
All results
Confidential
Page 4 of 82

Table 14.0x.07.0x: Baseline Disease characteristics

Previous: my_gposser
Safety Population - Not x: Overall population (per x=0)

	ALL	0/0x1 mg/kg	0/0x2 mg/kg	0/0x3 mg/kg	0/0x4 mg/kg	0/0x5 mg/kg	0/0x6 mg/kg
	N=64	N=24	N=24	N=24	N=24	N=24	N=24
Number of patients							
Time from last disease progression to first injection (months)							
x	44	x	x	x	3	3	
Mean	16.5	16.0	16.0	16.5	16.0	15.5	16.9
SD	09.96				34.05	34.06	
Median	16.5	16.0	16.0	16.5	16.0	15.5	16.9
Qx.01	15.0	15.0	16.0	16.0	16.0	15.5	16.9
Max	31.0	16.0	16.0	16.0	16.0	15.5	16.9

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All results
Confidential
Page 5 of 82

Table 14.0x.07.0x: Baseline Disease characteristics

Previous: my_gposser
Safety Population - Not x: Overall population (per x=0)

	ALL	0/0x1 mg/kg	0/0x2 mg/kg	0/0x3 mg/kg	0/0x4 mg/kg	0/0x5 mg/kg	0/0x6 mg/kg
	N=64	N=24	N=24	N=24	N=24	N=24	N=24
Number of patients							
Time from last disease progression to first injection (months)							
x	44	x	x	x	3	3	
Mean	16.5	16.0	16.0	16.5	16.0	15.5	16.9
SD	09.96				34.05	34.06	
Median	16.5	16.0	16.0	16.5			