

Figure 1A

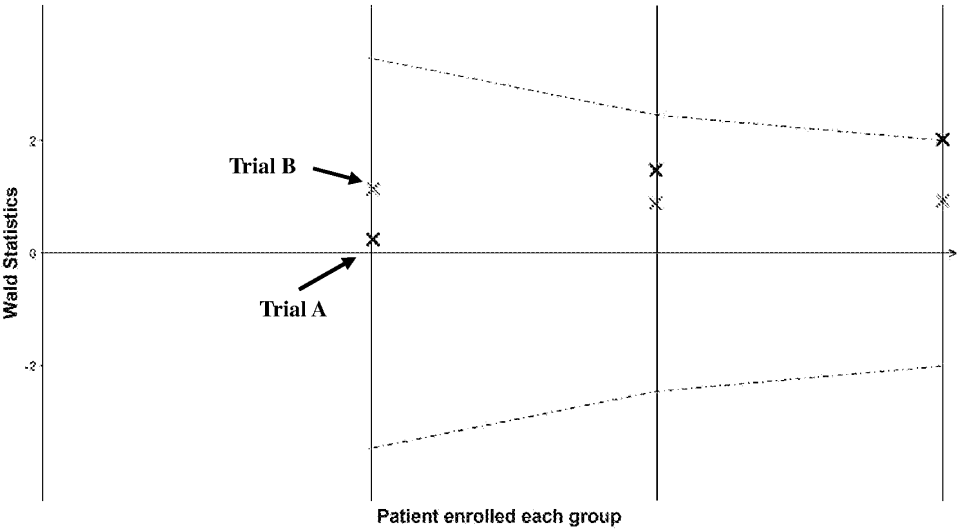
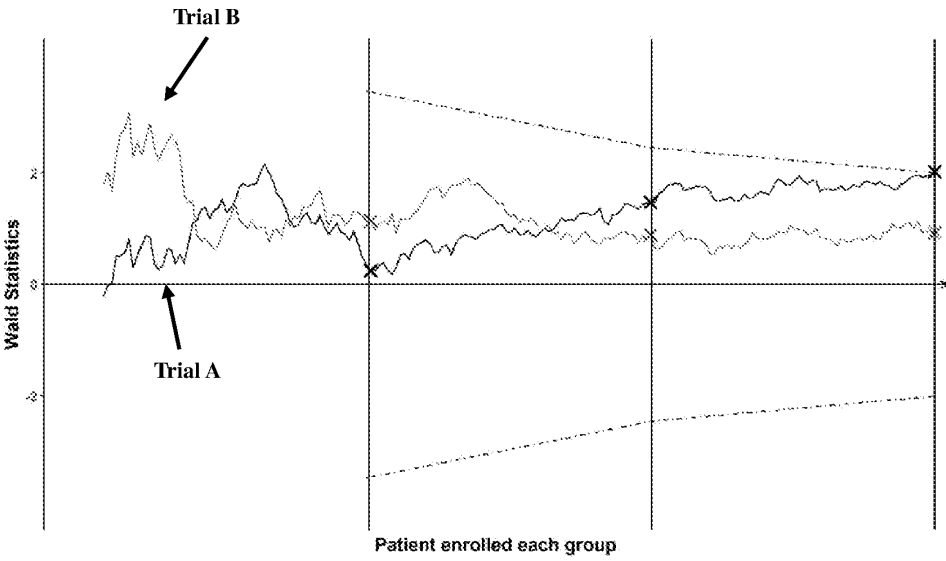


FIGURE 1B



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FIGURE 2

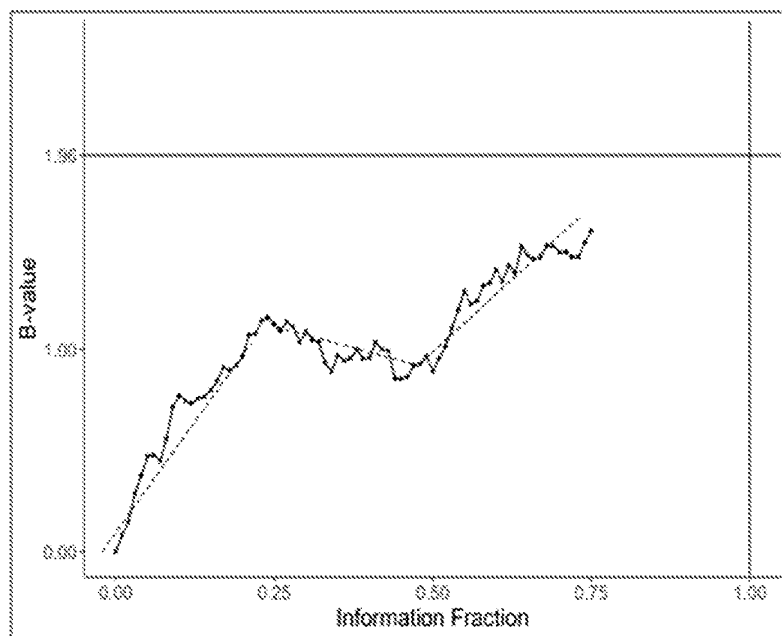


FIGURE 3A

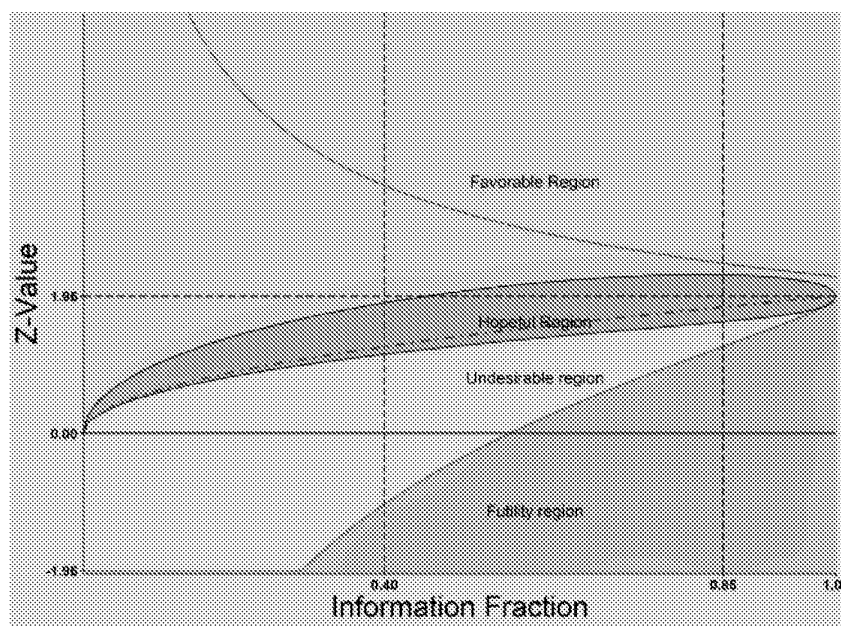


FIGURE 3B

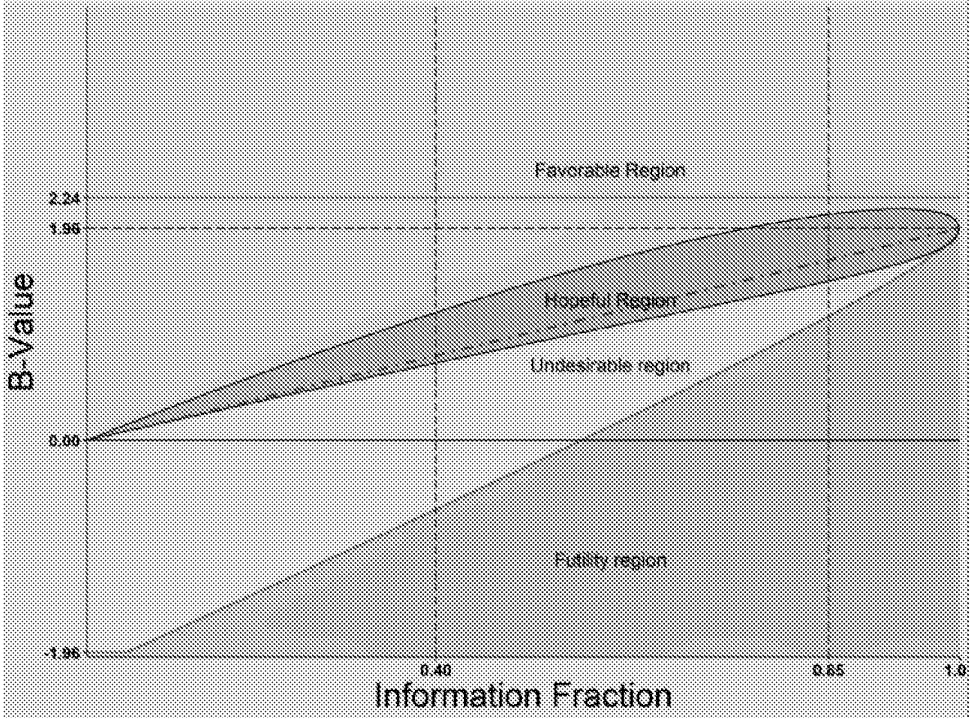


FIGURE 4A

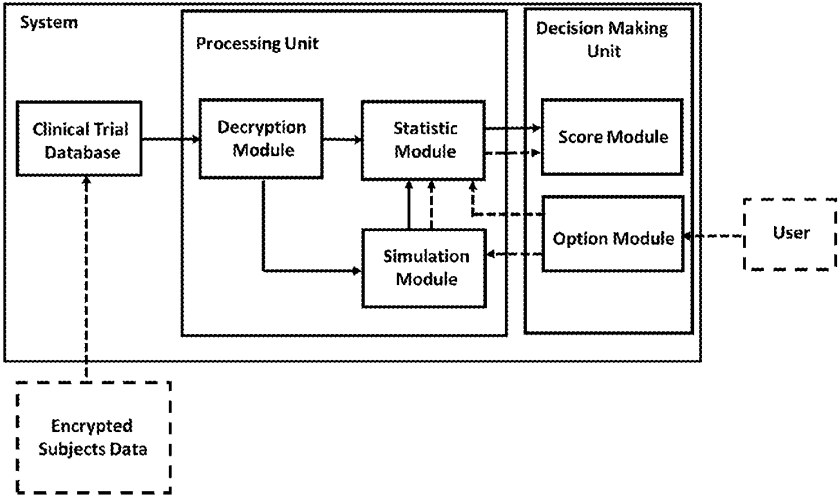


FIGURE 4B

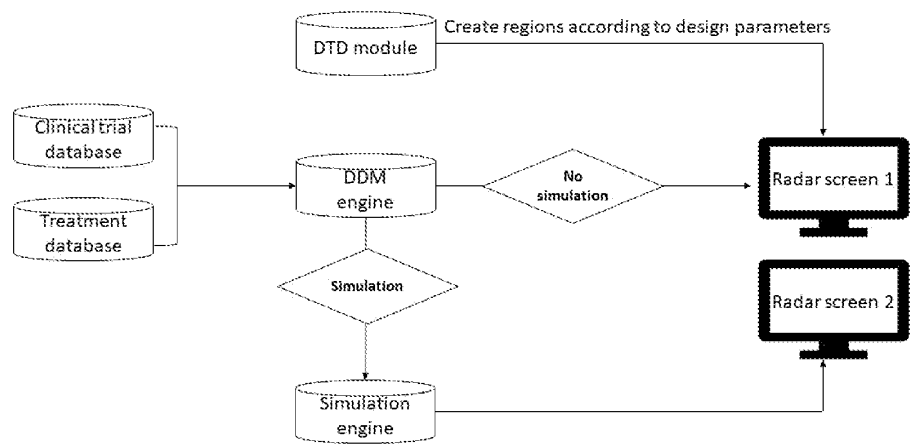


FIGURE 4C

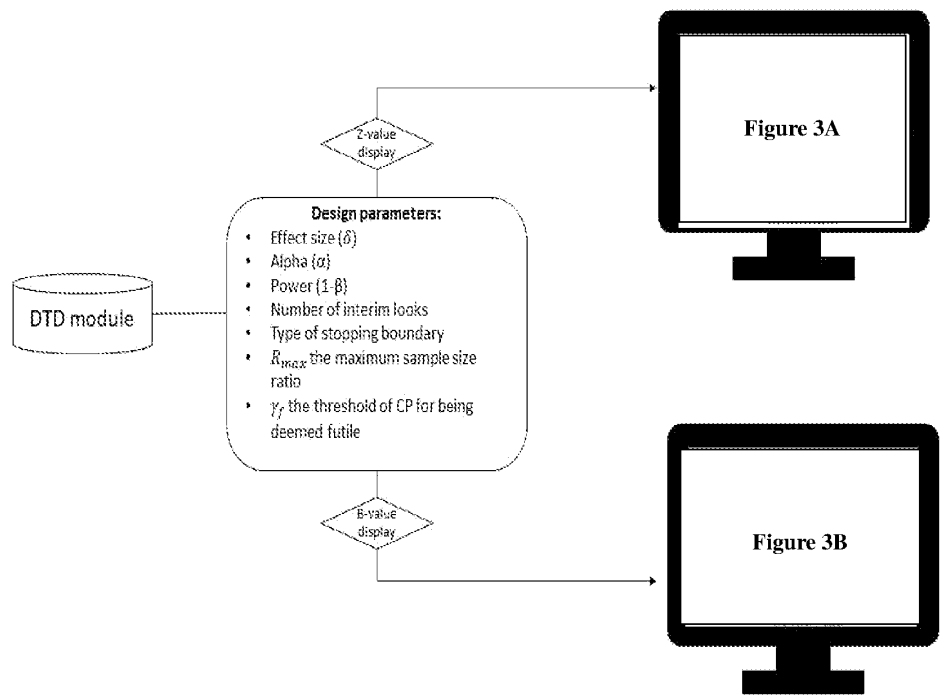


FIGURE 4D

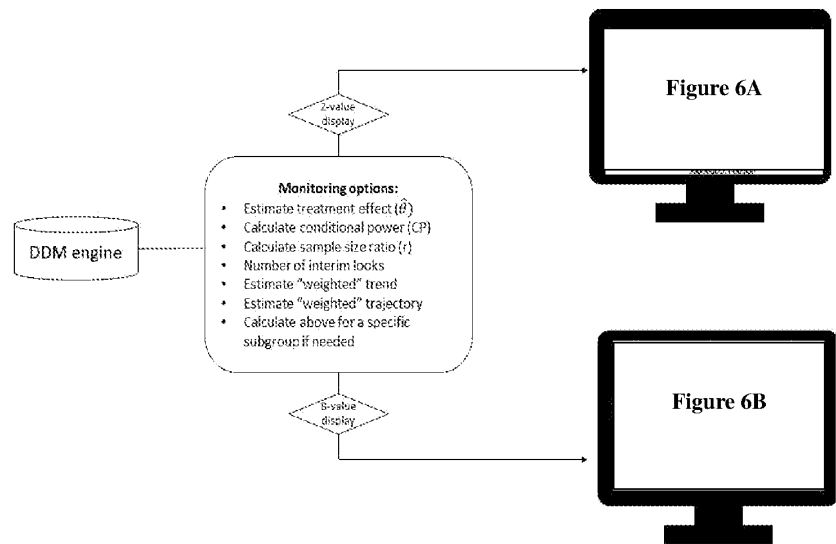
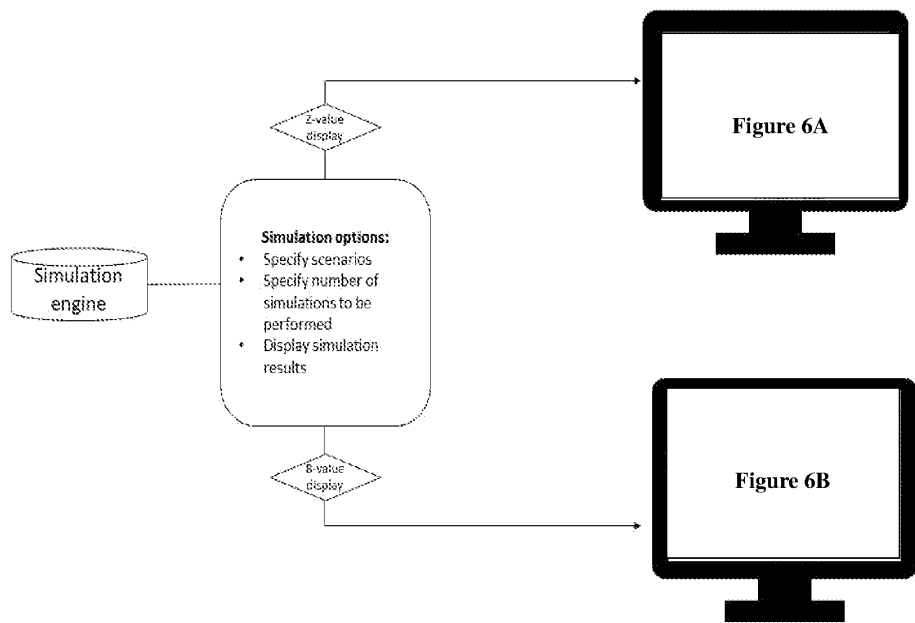


FIGURE 4E



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FIGURE 4F

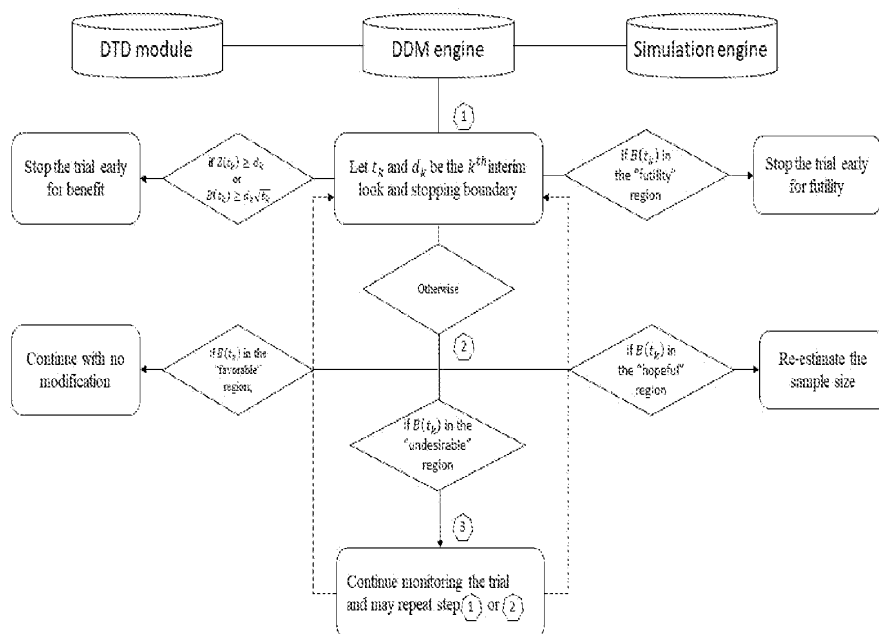
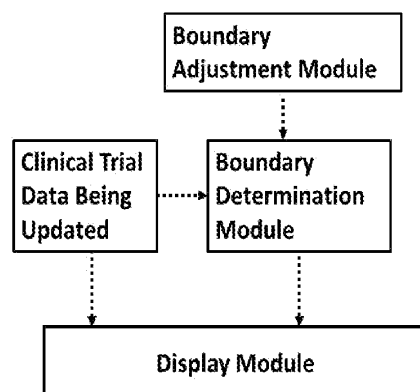


FIGURE 4G



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FIGURE 4H

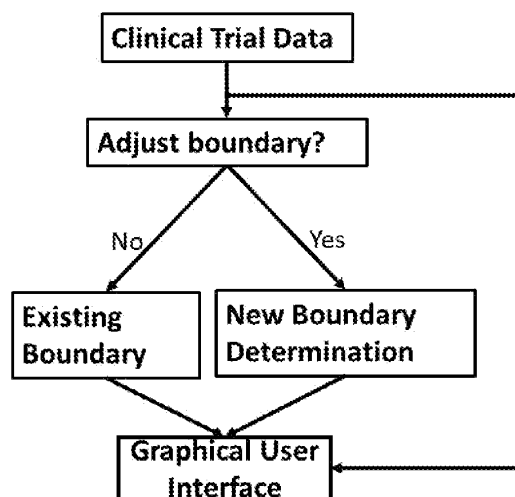


FIGURE 5A

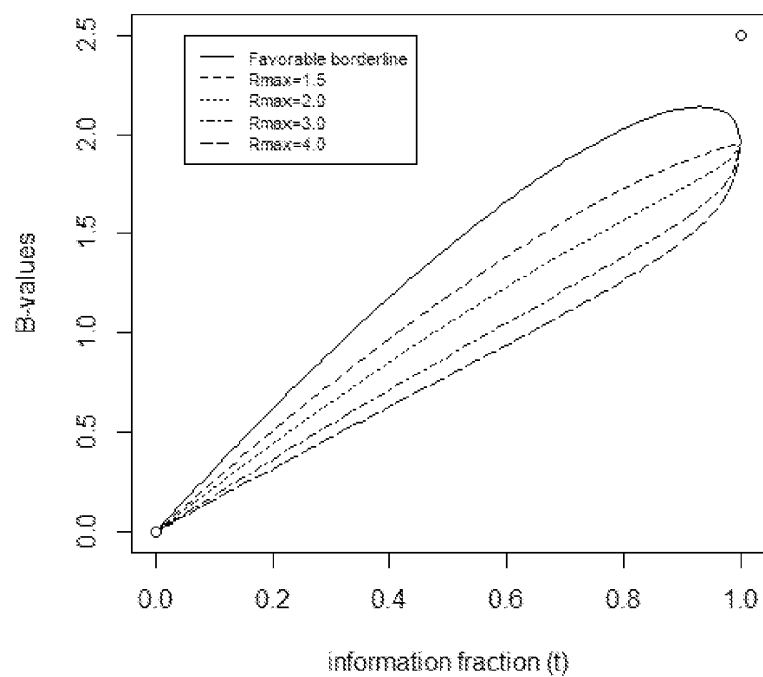


FIGURE 5B

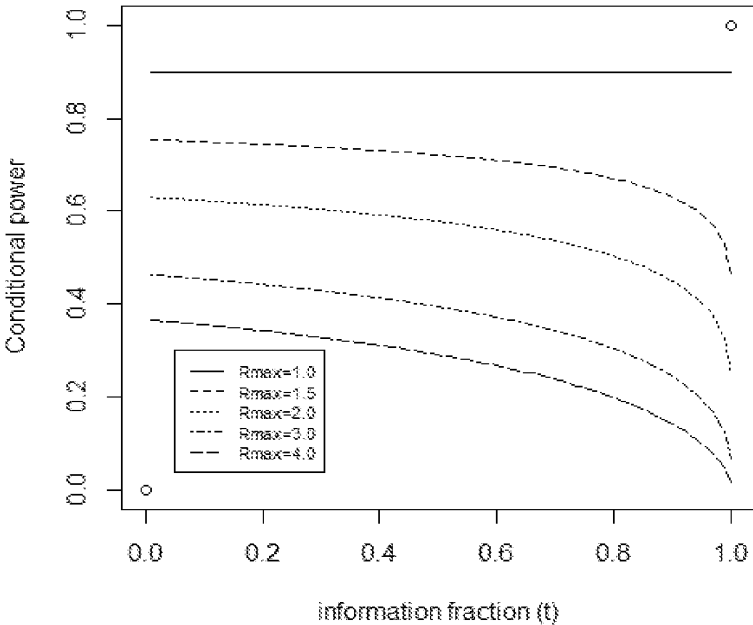


FIGURE 6A

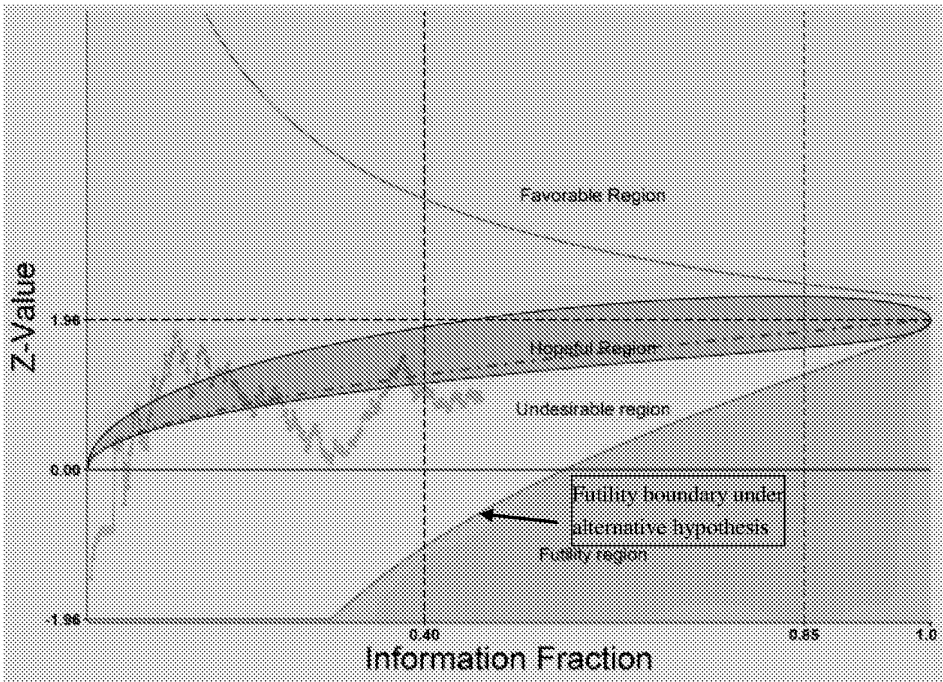


FIGURE 6B

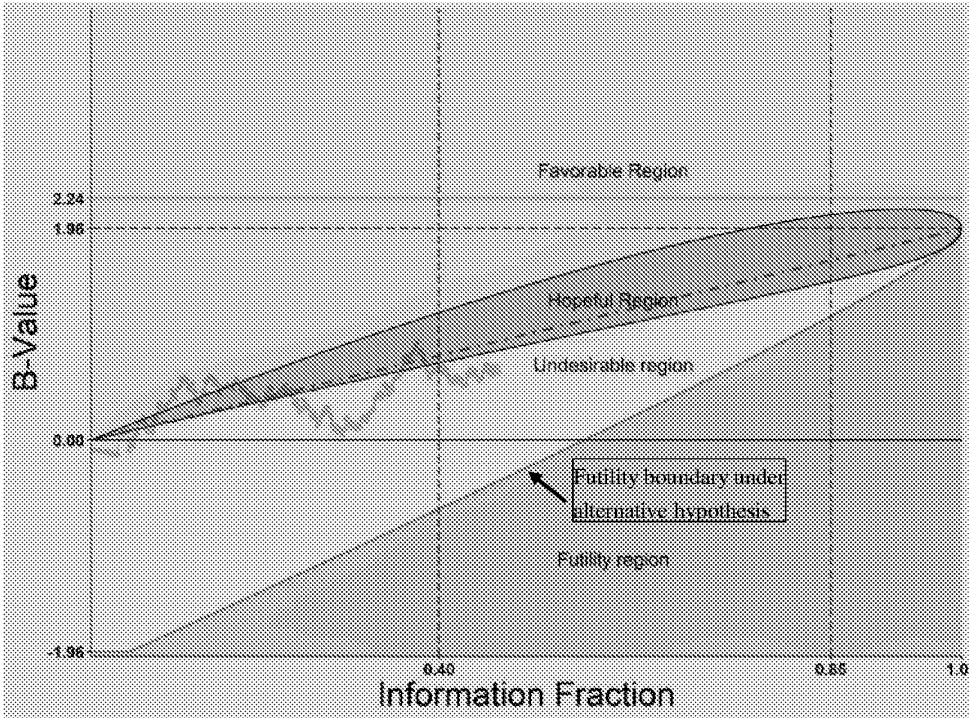


FIGURE 6C

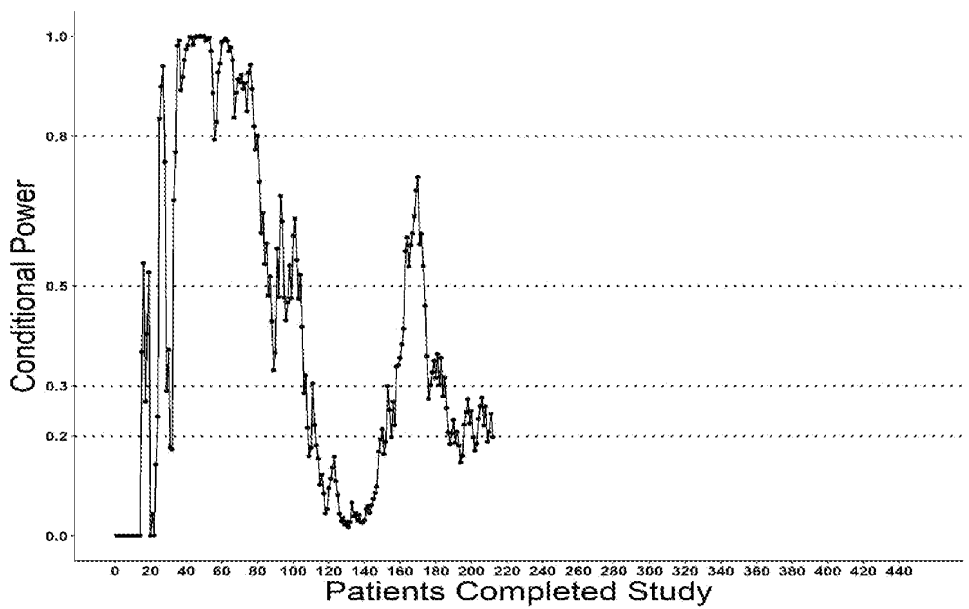
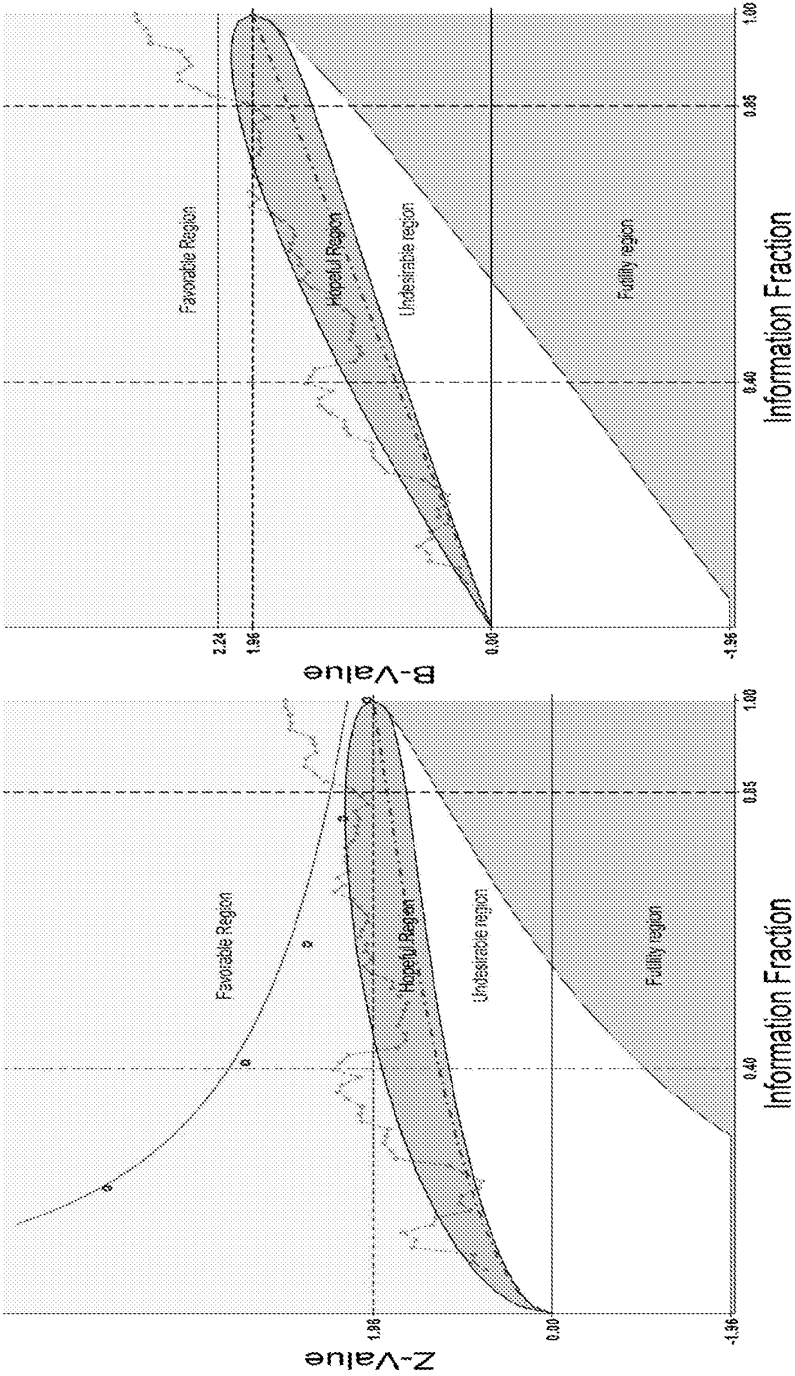


FIGURE 7A



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FIGURE 7B

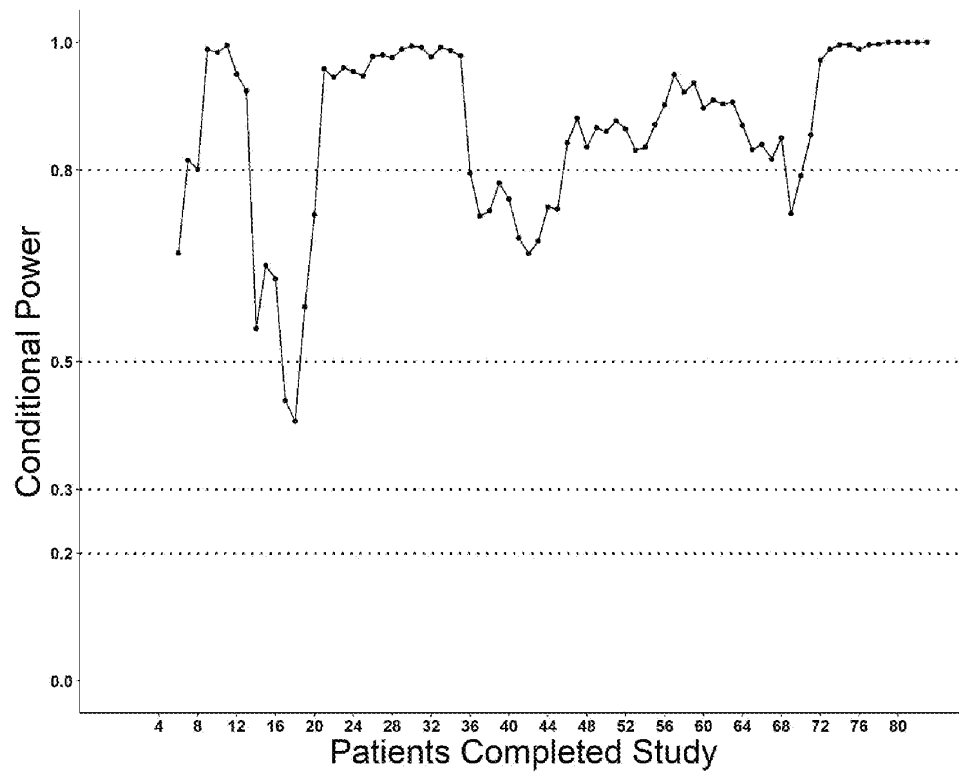
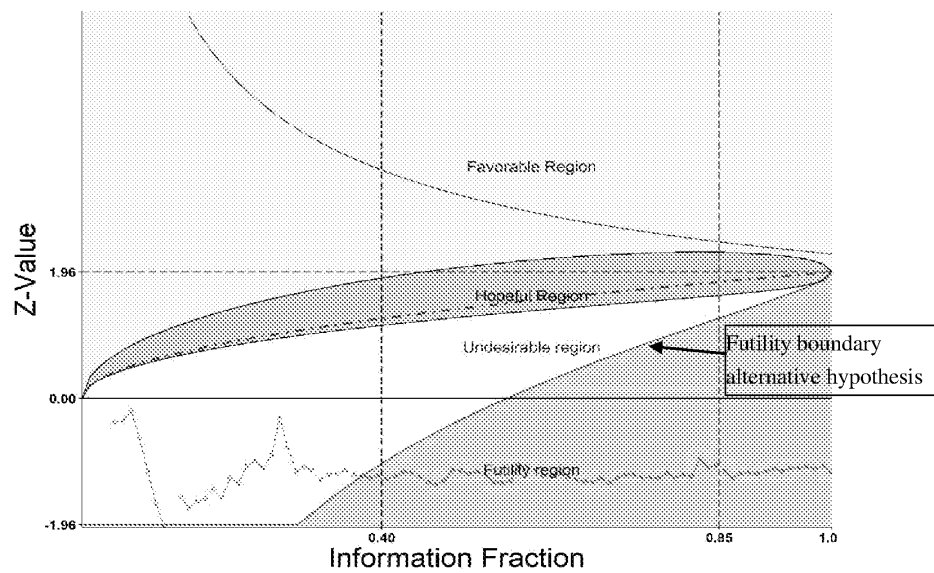


FIGURE 8A



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FIGURE 8B

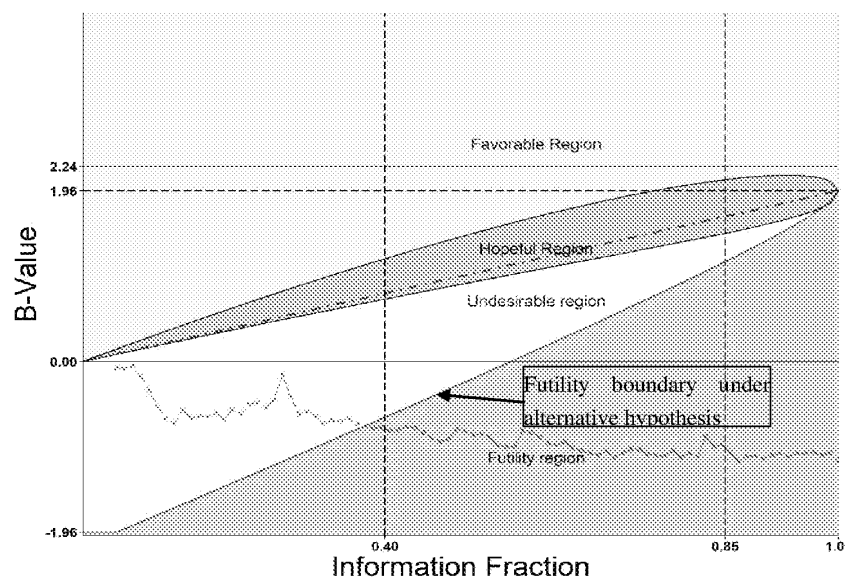
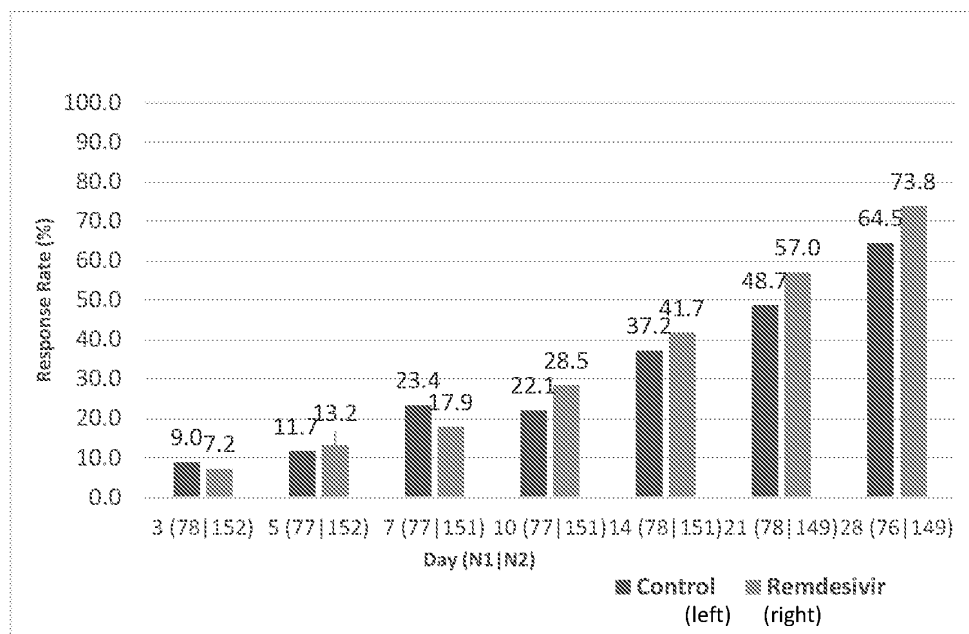


Figure 9



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Figure 10A

Design Parameter																	
Basic Parameter:		Sample Size	Group Ratio	Significant Level	Treatment Effect	Range	Power										
		240	1	0.025	0.4	0.15	0.9										
Early Efficacy Parameter:		Boundary Type	Phi	Number of Timepoints	Space												
☒ Yes ☐ No		O'Brien & Fleming	1	3	☒ Equal ☐ Unequal												
						<table border="1"> <thead> <tr> <th></th> <th>Time1</th> <th>Time2</th> <th>Time3</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>0.33</td> <td>0.67</td> <td>1.00</td> </tr> </tbody> </table>					Time1	Time2	Time3	1	0.33	0.67	1.00
	Time1	Time2	Time3														
1	0.33	0.67	1.00														
Futility Parameter:		Futility Rule	<=														
☒ Yes ☐ No		Conditional Power	0.05														
Sample Size Re-estimation:		Number of Simulation	Consecutive Points	Designed Power	Ncap												
☒ Yes ☐ No		1	1	0.9	600												
Monitoring Time Interval:						Add Parameters											

Figure 10B

Design Summary Table

☒ Sample_Size

☒ Group_Ratio(R)

☒ Significant_Level(Alpha)

☒ Treatment_Effect(Mu0)

☒ Range

☒ Power

☒ Boundary

☒ Phi

☒ Timepoints(K)

☒ Space

☒ Futility_Type

☒ Futility_Value

☒ Simulation

☒ Points

<

>

Simulate the Trial

Retrieve Record

Download

Show 5 entries

Search:

sample_size	R	Alpha	Mu0	range	power	boundary	phi	K	space	futility_type	futility_value
1	240	1	0.025	0.4	0.15	0.9	0.05	1	3	Equal	Conditional Power

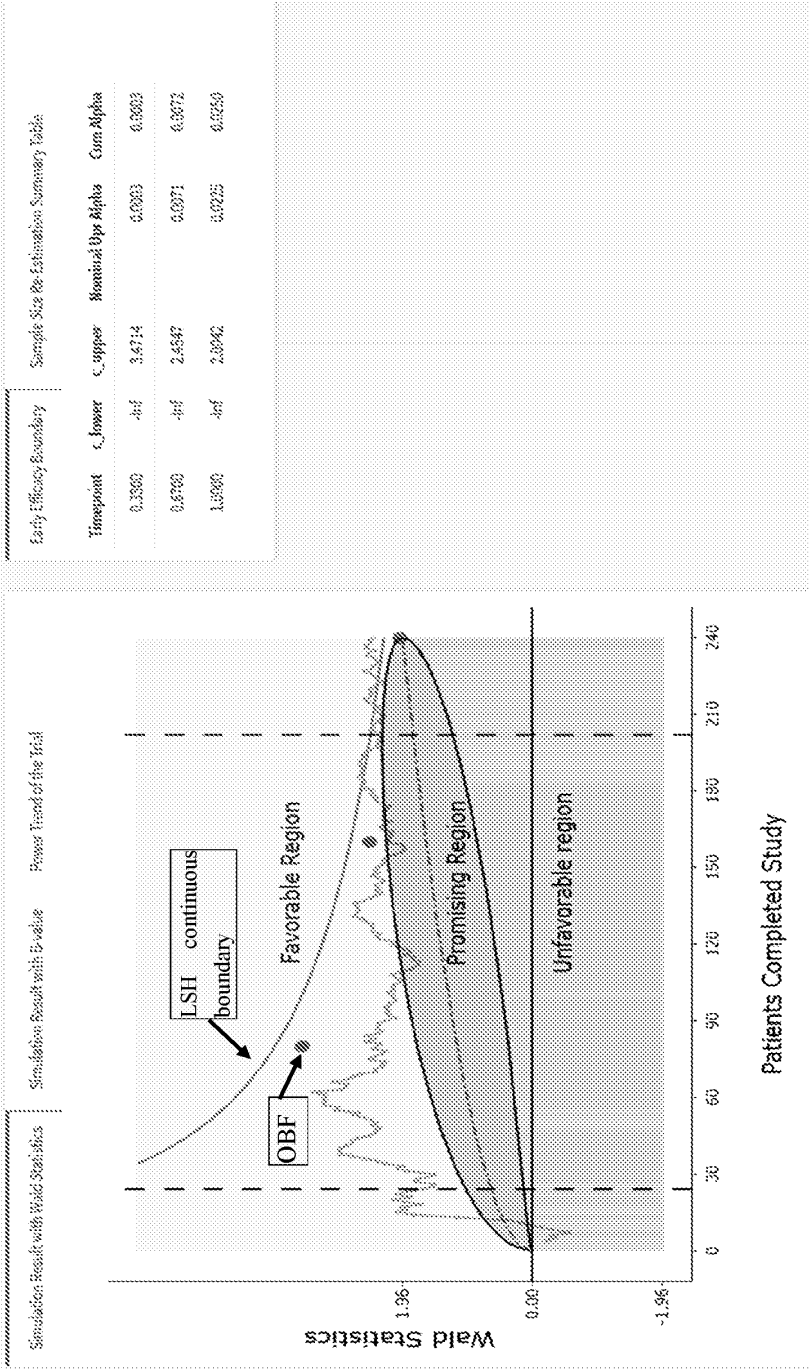
Showing 1 to 1 of 1 entries

Previous

1

Next

FIGURE 10C



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Figure 11A

Design Parameter														
Basic Parameter:														
Sample Size	Group Ratio	Significance Level	Treatment Effect											
300	1	0.025	0.4											
Efficacy boundary:														
☒ Yes ☐ No	Boundary Type	Phi	Number of looks											
	Open & Fleming	1	5											
	<table border="1"> <thead> <tr> <th>Time1</th> <th>Time2</th> <th>Time3</th> <th>Time4</th> <th>Time5</th> </tr> </thead> <tbody> <tr> <td>0.20</td> <td>0.40</td> <td>0.60</td> <td>0.80</td> <td>1.00</td> </tr> </tbody> </table>	Time1	Time2	Time3	Time4	Time5	0.20	0.40	0.60	0.80	1.00		Space ☒ Equal ☐ Unequal	
Time1	Time2	Time3	Time4	Time5										
0.20	0.40	0.60	0.80	1.00										
Reference efficacy boundary:														
☒ Yes ☐ No	Boundary Type	Phi												
	Continuous O'Brien & Fleming Type	1												
Futility Parameter:														
☒ Yes ☐ No	Futility Rule	<=												
	Conditional Power under alternative	0.05												
Sample Size Re-estimation:														
☒ Yes ☐ No	Rejection Rule	>=		Desired Power										
	New sample size	0.00		0.9										
Monitoring Time Interval:														

Figure 11B

Data Source			
Input Data:			
Upload data. Choose SAS data file			
Browse... c:\RiskAssessment\...			
Variable Name			
Population: (e.g., SAFETY)	SAFETY (Safety Population Flag)	Value:	Y
Variable Name			
Endpoint: (e.g., PARACET)	PARACET (Paracetamol Code)	Value:	0.5
Variable Name			
Visit: (e.g., ANALYSIS)	ANALYSIS (Analysis Visit (N))	Value:	1.0
Variable Name			
Analysis value: (e.g., PCHG, ANSL)	PCHG (Percent Change from Baseline)		
Treatment Group:			
(e.g., TRT001)	TRT001 (Actual Treatment (N))	Treatment	2
Context			
			1
Analysis Collection Time:			
(e.g., LBSTC)	LBSTC (Date/Time of Specimen)	Type	Character

Figure 11C

Design Summary Table

☒ Sample_Size

☒ Group_Ratio(R)

☒ Significant_Level(Alpha)

☒ Treatment_Effect(Mu0)

☒ Discrete_Boundary

☒ Boundary_type

☒ choice_of_continuous_boundary

☒ Continuous_Boundary

☒ Phi

☒ Phi2

☒ Timepoints(K)

☒ Group

Monitor the Trial

Show 5 entries

Search:

sample_size	R	Alpha	Mu0	choice_ee	boundary	choice_cont_ee	cont_boundary	phi	phi2	K	space	
1	100	1	0.025	0.4	Yes	DBF	No	DBF_cont_Sim	1	1	5	Equal

Showing 1 to 1 of 1 entries

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Remove Record

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Figure 11D

