

## **Report for ANKLE DSMB: Prepared APRIL 2010**

### **Part A: Number of Patients Included and Excluded**

There have been 224 patients randomized online as of April 26, 2010.

**Figure 1** presents the overall study status. **Figure 2** shows the total number of enrolled patients by month.

**Table 1** presents the starting dates of recruitment of the 10 centers in the study, and a month-by-month picture of the recruitment each center has achieved.

### **Part B: Summary of Patient Randomization**

**Table 2a** presents the number of patients by treatment assignment. 108 patients have been randomized to Treatment A (**48%**) and 116 to Treatment B (**52%**) **Table 2b-c** cross-references each patient's online randomization with the treatment indicated on the Surgical Summary form. Of the 224 patients enrolled, 9 (crossed treatments) (4.0%).

### **Part C: Patients lost to follow-up, withdrew consent, ineligible**

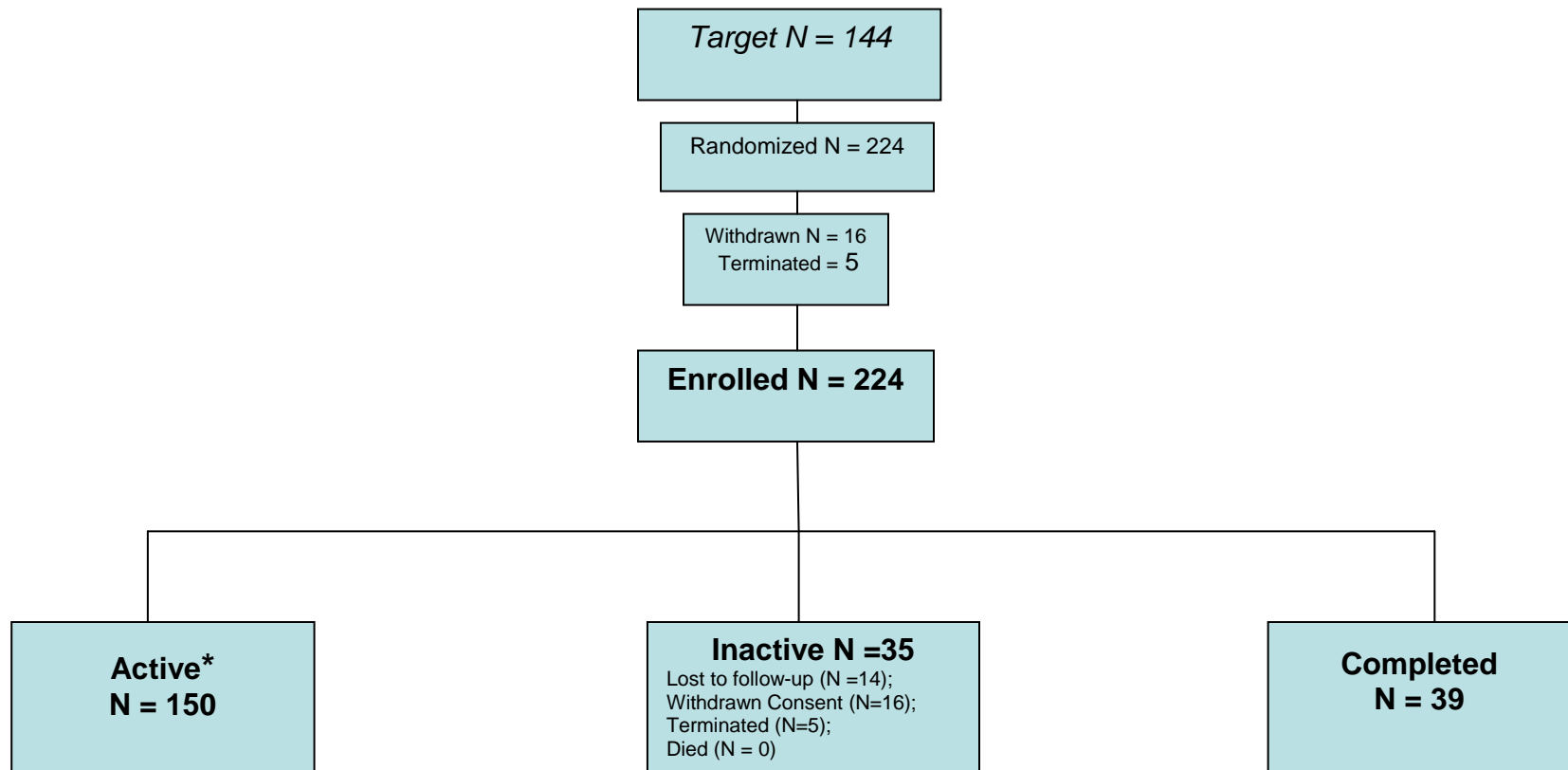
**Table 3a** presents the patients that were lost to follow-up, withdrew consent, or were removed due to an ineligible fracture. **Table 3b-d** shows the number of patients by center and fracture type that were lost to follow-up, withdrew consent, and were declared ineligible. There have been 14 patients lost to follow-up. 16 patients withdrew consent after randomization, 3 Patients were terminated by study team and 1 patient was removed due to an ineligible fracture pattern leaving a total active enrollment of 150.

### **Part D: Summary of Adverse Events**

**Table 4a** shows the event rates as of April 26, 2010. There have been 18 reported Adverse Events in 11 study patients, resulting in a (12.0) percent AE rate in Treatment A (N=108), and a (4.3) percent AE rate for Treatment B (N=116). No Serious Adverse Events have been reported. Descriptions of the reported Adverse Events are presented in **Table 4b**.

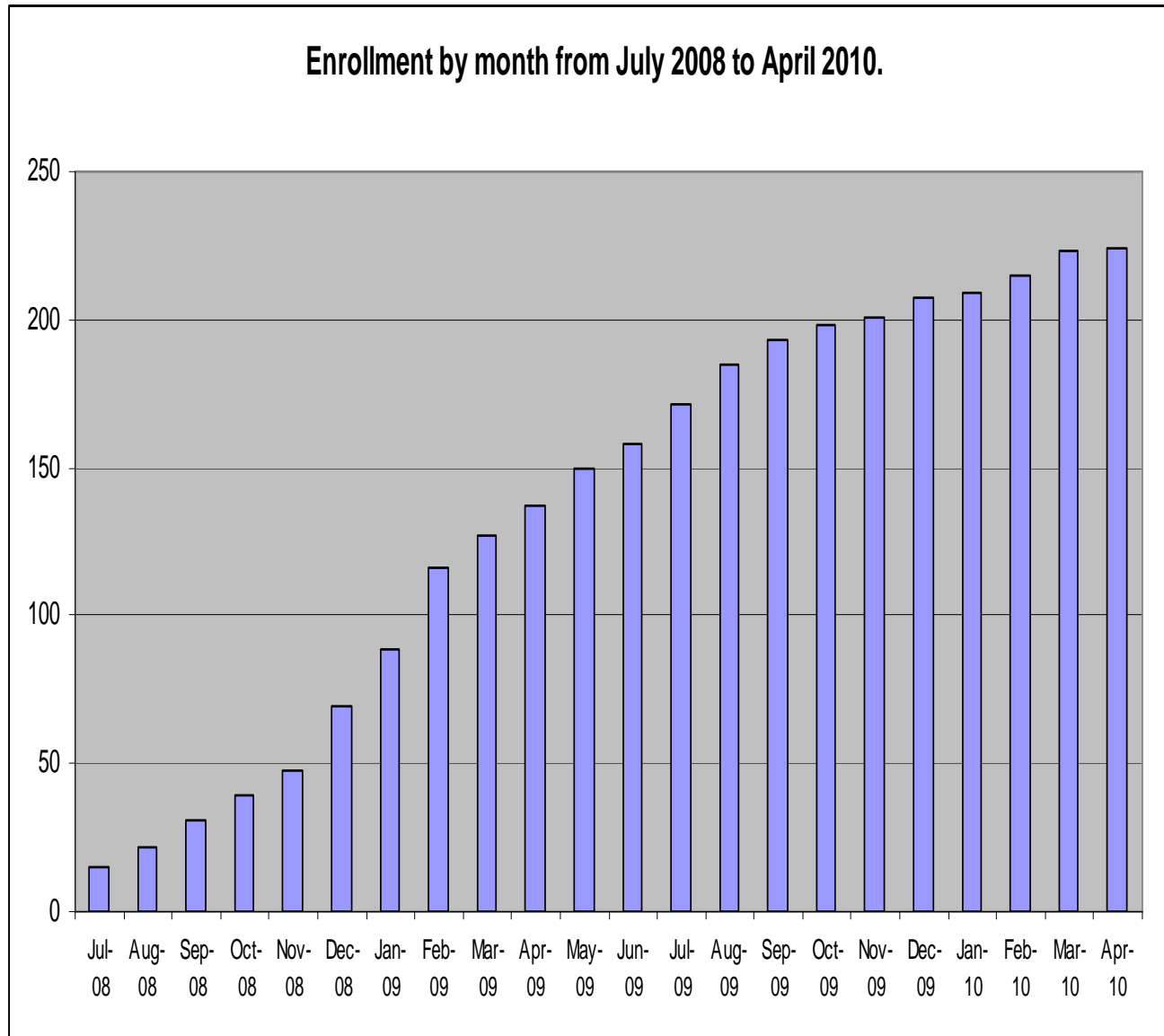
Figure 1: Overall study status

## Overall Study Status



\* 43 have currently missed appointments and are likely lost.

**Figure 2: Cumulative enrollment by month**



**Table 1: Enrollment July 2008 through March 2009**

<b>CenterID</b>	<b>Approval Date</b>	<b>Jul-08</b>	<b>Aug-08</b>	<b>Sep-08</b>	<b>Oct-08</b>	<b>Nov-08</b>	<b>Dec-08</b>	<b>Jan-09</b>	<b>Feb-09</b>	<b>Mar-09</b>
01	10-Sep-08	-	-	2	1	4	3	5	5	1
02	27-Mar-08	5	1	0	2	0	4	2	1	1
03	6-Jun-08	0	0	0	0	0	0	0	1	0
04	26-Sep-08	-	-	-	0	0	0	0	0	0
05	26-May-08	4	4	4	3	1	4	5	1	3
06	01-Feb-09	-	-	-	-	-	-	-	0	0
07	08-Jan-09	-	-	-	-	-	-	0	6	2
08	03-Jun-08	6	2	3	2	4	10	8	12	4
09	08-Jan-09	0	0	0	0	0	0	0	0	0
10	09-May-08	0	0	0	0	0	0	2	1	0
<b>Total Sites</b>		<b>5</b>	<b>5</b>	<b>7</b>	<b>8</b>	<b>8</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>10</b>
<b>Monthly Enrollment</b>		<b>15</b>	<b>7</b>	<b>9</b>	<b>7</b>	<b>9</b>	<b>21</b>	<b>22</b>	<b>27</b>	<b>11</b>
<b>Cumulative Enrollment</b>		<b>15</b>	<b>22</b>	<b>31</b>	<b>39</b>	<b>48</b>	<b>69</b>	<b>89</b>	<b>116</b>	<b>127</b>

**Table 1: Enrollment April 2009 through October 2009**

<b>Center ID</b>	<b>Approval Date</b>	<b>April-09</b>	<b>May-09</b>	<b>June-09</b>	<b>July-09</b>	<b>Aug-09</b>	<b>Sep-09</b>	<b>Oct-09</b>
01	10-Sep-08	0	1	1	0	0	0	0
02	27-Mar-08	0	0	0	2	0	1	0
03	6-Jun-08	2	0	0	2	0	1	0
04	26-Sep-08	0	0	0	0	0	0	0
05	26-May-08	2	3	4	2	3	4	1
06	01-Feb-09	0	0	0	0	2	0	0
07	08-Jan-09	3	0	1	7	9	2	2
08	03-Jun-08	2	6	0	0	0	0	0
09	08-Jan-09	0	3	2	0	0	0	0
10	09-May-08	1	0	0	0	0	0	2
<b>Total Sites</b>		<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>
<b>Monthly Enrollment</b>		<b>10</b>	<b>13</b>	<b>8</b>	<b>13</b>	<b>14</b>	<b>8</b>	<b>5</b>
<b>Cumulative Enrollment</b>		<b>137</b>	<b>150</b>	<b>158</b>	<b>171</b>	<b>185</b>	<b>193</b>	<b>198</b>

**Table 1: Enrollment through November 2009 to April 2010**

<b>Center ID</b>	<b>Approval Date</b>	<b>Nov-09</b>	<b>Dec-09</b>	<b>Jan-10</b>	<b>Feb-10</b>	<b>Mar-10</b>	<b>Apr-10</b>
01	10-Sep-08	0	0	0	0	0	0
02	27-Mar-08	0	0	1	1	2	0
03	6-Jun-08	0	0	0	0	0	1
04	26-Sep-08	0	0	0	0	0	0
05	26-May-08	1	1	0	0	0	0
06	01-Feb-09	0	1	0	0	0	0
07	08-Jan-09	1	1	1	0	0	0
08	03-Jun-08	0	0	0	2	3	0
09	08-Jan-09	0	3	0	0	2	0
10	09-May-08	1	0	0	3	1	0
<b>Total Sites</b>		<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>
<b>Monthly Enrollment</b>		<b>3</b>	<b>6</b>	<b>2</b>	<b>6</b>	<b>8</b>	<b>1</b>
<b>Cumulative Enrollment</b>		<b>201</b>	<b>207</b>	<b>209</b>	<b>215</b>	<b>223</b>	<b>224</b>

**Table 2a: Enrollment by Treatment Assignment**

<b>Center ID</b>	<b>Treatment A</b>	<b>Treatment B</b>	<b>Total</b>
<b>01</b>	12	11	23
<b>02</b>	10	13	23
<b>03</b>	3	4	7
<b>04</b>	0	0	0
<b>05</b>	25	25	50
<b>06</b>	1	2	3
<b>07</b>	17	18	35
<b>08</b>	32	33	65
<b>09</b>	3	4	7
<b>10</b>	5	6	11
<b>TOTAL</b>	<b>108</b>	<b>116</b>	<b>224</b>

**Table 2b : Patients with different randomized treatment than indicated on surgical summary**

<b>Subject ID</b>	<b>Site</b>	<b>Randomized Treatment</b>	<b>Surgical Summary</b>
03-***-0016	02	A	B
03-***-0003	05	A	B
03-***-0008	05	B	A
03-***-0034	05	A	B
03-***-0027	07	A	B
03-***-0014	07	B	A
03-***-0054	08	A	B
03-***-0047	08	B	A

**Table 2c: Summary of patients that crossed treatment groups by Center**

<b>Center</b>	<b>Number of Patients Enrolled</b>	<b>Crossed from A to B</b>	<b>Crossed from B to A</b>
<b>01</b>	23	0	0
<b>02</b>	23	1	0
<b>03</b>	7	2	0
<b>04</b>	0	0	0
<b>05</b>	50	1	1
<b>06</b>	3	0	0
<b>07</b>	35	1	1
<b>08</b>	65	1	1
<b>09</b>	7	0	0
<b>10</b>	11	0	0
<b>TOTAL</b>	<b>224</b>	<b>6</b>	<b>3</b>

**Table 3a: Patients lost to follow-up, withdrew consent, ineligible**

<b>Subject-ID</b>	<b>Center-ID</b>	<b>Date of Enrollment</b>	<b>Date of Last Follow-up</b>	<b>Reason</b>
03-***-0017	01	4-Feb-09	30-Apr-09	Lost to f/u
03-***-0021	01	4-Mar-09	26-May-09	Lost to f/u
03-***-0001	02	1-Jul-08	12-Aug-08	Lost to f/u
03-***-0003	02	23-Jul-08	13-Jan-09	Lost to f/u
03-***-0005	02	31-Jul-08	19-Aug-08	Lost to f/u
03-***-0006	02	4-Aug-08	3-Feb-09	Lost to f/u
03-***-0018	02	28-Jul-09	No F/u	Withdrew Consent.
03-***-0001	03	16-Feb-09	NO F/U	Lost to f/u
03-***-0002	03	17-Apr-09	29-Apr-09	Terminated
03-***-0004	03	7-Jul-09	NO F/U	Withdrew Consent.
03-***-0012	05	30-Sep-08	N/A	Withdrew consent
03-***-0007	08	11-Aug-08	No f/u	Lost to f/u
03-***-0008	08	26-Aug-08	19-Nov-08	Withdrew consent
03-***-0011	08	12-Sep-08	8-Dec-08	Lost to f/u
03-***-0012	08	6-Oct-08	6-Oct-08	Withdrew consent
03-***-0015	08	2-Nov-08	No f/u	Lost to f/u
03-***-0016	08	2-Nov-08	11-May-09	Withdrew consent
03-***-0020	08	15-Dec-08	29-Jan-09	Withdrew consent
03-***-0021	08	15-Dec-08	9-Mar-09	Lost to f/u
03-***-0024	08	18-Dec-08	10-Jun-09	Withdrew consent
03-***-0025	08	18-Dec-08	No f/u	Withdrew consent
03-***-0028	08	31-Dec-08	3-Apr-09	lost to f/u
03-***-0029	08	1-Jan-09	2-Apr-09	lost to f/u
03-***-0034	08	9-Jan-09	19-Mar-09	Withdrew consent
03-***-0035	08	18-Jan-09	2-Mar-09	Lost to f/u

<b>Subject-ID</b>	<b>Center-ID</b>	<b>Date of Enrollment</b>	<b>Date of Last Follow-up</b>	<b>Reason</b>
03-***-0036	08	20-Jan-09	15-Jul-09	Withdrew consent
03-***-0037	08	1-Feb-09	31-Jul-09	Withdrew consent
03-***-0038	08	2-Feb-09	No F/U	in eligible
03-***-0039	08	2-Feb-09	28-May-09	Withdrew consent
03-***-0042	08	3-Feb-09	30-Apr-09	Withdrew consent
03-***-0045	08	14-Feb-09	11-Jun-09	Withdrew consent
03-***-0046	08	17-Feb-09	7-May-09	Withdrew consent
03-***-0002	09	6-May-09	No F/u	Withdrew consent
03-***-0004	10	20-Apr-09	2-Jun-09	Lost to f/u
03-***-0002	10	27-Jan-09	28-Jul-09	Lost to f/u
03-***-0005	10	21-Oct-09	9-Dec-09	Terminated
03-***-0006	10	22-Oct-09	7-Dec-09	Terminated

**Table3b: Ineligible Patients by Fracture Type and Treatment Assignment**

CenterID	Treatment		Total
	A	B	
01	0	0	0
02	0	0	0
03	0	0	0
04	0	0	0
05	0	0	0
06	0	0	0
07	0	0	0
08	0	1	1
09	0	0	0
10	0	0	0
<b>TOTAL</b>	<b>0</b>	<b>1</b>	<b>1</b>

**Table3c Withdrawn Patients by Fracture Type and Treatment Assignment**

CenterID	Treatment		Total
	A	B	
01	0	0	0
02	0	1	1
03	1	0	1
04	0	0	0
05	0	0	0
06	0	0	0
07	0	0	0
08	8	5	13
09	0	1	1
10	0	0	0
<b>TOTAL</b>	<b>9</b>	<b>7</b>	<b>16</b>

**Table 3d: Patients Lost to Follow-up by Fracture Type and Treatment Assignment**

CenterID	Treatment		Total
	A	B	
01	0	2	2
02	1	3	4
03	0	1	1
05	0	0	0
06	0	0	0
07	0	0	0
08	2	5	7
09	0	0	0
10	0	0	0
<b>TOTAL</b>	<b>3</b>	<b>11</b>	<b>14</b>

**Table 4a: Adverse Event rates by treatment**

	# Patients with Events	Total Patients (Rate%)
Treatment A	13	108 (12.0)
Treatment B	<b>5</b>	<b>116 (4.3)</b>
<b>Total</b>	18	224 (8)

**Table 4b: Adverse Event descriptions**  
*Total Events = 18*

Subject-ID	Center ID	Treatment	Date	Description of Event	Severity of Event	Device Related?
03-***-0006	05	A	9-Sep-08	SUPERFICIAL INFECTION	MILD	POSSIBLY RELATED
03-***-0006	05	A	30-Sep-08	DEEP INFECTION	MILD	POSSIBLY RELATED
03-***-0006	05	A	6-Oct-08	DEEP INFECTION	MODERATE	POSSIBLY RELATED
03-***-0006	05	A	30-Oct-08	SUPERFICIAL INFECTION	MILD	POSSIBLY RELATED
03-***-0001	08	A	9-Jul-08	INFECTED SUPERFICIAL WOUND (not at surgical site)	MILD	DEFINITELY NOT RELATED
03-***-0001	08	A	11-Jul-08	DVT	MODERATE	POSSIBLY RELATED
03-***-0001	08	A	31-Jul-08	DVT	MODERATE	POSSIBLY RELATED
03-***-0002	08	A	4-Nov-08	INFECTED SUPERFICIAL WOUND (not at surgical site)	MILD	DEFINITELY NOT RELATED
03-***-0026	08	A	01-Apr-09	CONSTRUCT LOOSENING-DISTAL TO FRACTURE	NOT SERIOUS	POSSIBLY RELATED
02-***-0001	07	A	28-JUL-09	SURGICAL SITE/ORTHOPAEDIC	MILD	PROBABLY NOT RELATED

<b>02-***-0022</b>	07	A	09-Sep-09	INFECTION MINOR	MILD	POSSIBLY RELATED
<b>02-***-0027</b>	07	A	17-Aug-09	PATIENT REQUIRED A LATERAL PLATE WHEN RANDOMIZED TO ANTIGLIDE	NOT SERIOUS	DEFINITELY NOT RELATED
<b>03-***-0005</b>	08	A	03-Aug-09	PAINFUL IMPALNT -PLATE	MILD	DEFINITELY RELATED
<b>03-***-0010</b>	08	B	13-Sep-08	MAYOCARDIAL INFARCTION	MODERATE	DEFINITELY NOT RELATED
<b>03-***-0010</b>	08	B	20-Nov-08	FRACTURED OTHER ANKLE (RIGHT)	MODERATE	DEFINITELY NOT RELATED
<b>03-***-0010</b>	08	B	19-Feb-09	Non-Union	SEVERE	POSSIBLY RELATED
<b>03-***-0009</b>	02	B	17-Feb-09	NECROSIS/WOUND SLOUGH	MILD	POSSIBLY RELATED
<b>02-***-0025</b>	07	B	15-Sep-09	DEEP INFECTION	MODERATE	NOT RELATED