

**IIHT  
SCHEDULE OF ACTIVITIES**

Data Form	Level #	Screening Visit (SC)	Baseline Visit (BL)	Visit 01	Visit 02	Visit 03	Visit 04	Visit 05	T01	T02	Visit 06	Visit 07	Visit 08	Visit 09	Final Visit (V10/FNL)	Unscheduled Visit (U01, U02, etc.)	Premature Withdrawal Visit (PW/FNL)
		(-2-7 days)	Week 0 (Day 0)	Month 1 (± 7 days)	Month 2 (± 7 days)	Month 3 (± 7 days)	Month 4.6 (± 7 days)	Month 8 (± 7 days)	Phone call 7 Moc	Phone call 8 Moc	Month 9 (± 7 days)	Month 12 (± 7 days)	Month 24 (± 1 month)	Month 36 (± 1 month)	Month 48 (± 1 month)		
Informed Consent		X	X (review)														
Log of Investigators, Study Staff, Related Duties		X															
Confidential Subject/Control Identification Code List		X															
Screening/Demographics	02	X															
Inclusion/Exclusion - IIH	04	X	X (review)														
Randomization			X														
Socio-Economics (NORDIC)	08	X															
Medical History Form (NORDIC)	10	X	X														
General Physical Exam	12	X														X <sup>1</sup>	
Headache Evaluation	14		X														
Medical Follow-up	16			X	X	X	X	X			X	X	X	X	X	X	X
Neurological Exam	18	X															
Lumbar Puncture	20	X						X									
Berlin Sleep Apnea Questionnaire	22		X														
HIT-6	24		X					X			X				X		X
Physical Activity Questions	26		X					X			X				X		X
Visual Functioning Questionnaire - 25	28		X					X			X				X		X
Neuro-Ophthalmic 10 Question Supplement	30		X					X			X				X		X
SF-36	32		X					X			X				X		X
Vital Signs (NORDIC)	34		X	X	X	X	X	X			X	X	X	X	X	X	X
Humphrey Perimetry Visual Field Grading	36	X <sup>2</sup>		X	X	X	X	X <sup>2</sup>			X	X	X	X	X	X <sup>1</sup>	X
Ocular Examination	38	X		X	X	X	X	X			X	X	X	X	X	X <sup>1</sup>	X
Refraction/visual Acuity	40	X	X	X	X	X	X	X			X	X	X	X	X	X <sup>1</sup>	X
OCT Substudy - Low Contrast Visual Acuity	42	X <sup>4</sup>				X <sup>4</sup>		X <sup>4</sup>				X <sup>4</sup>					
Fundus Photo Grading Log Part 1	44	X		X	X	X	X	X			X	X	X	X	X	X <sup>1</sup>	X
Fundus Photo Grading Log Part 2	46	X						X			X						
Laboratory Procedures	48	X		X	X	X		X <sup>5</sup>	X <sup>3</sup>	X <sup>3</sup>						X <sup>1</sup>	X <sup>5</sup>
Blood Sample for DNA		X															
Vitamin A test		X						X									
Pregnancy Form	50		X														
Dietary Intervention	52		X	X	X	X	X	X			X	X	X	X	X		X
Health Services Utilization Baseline	54		X														
Health Services Utilization Follow-up	56			X	X	X	X	X			X	X	X	X	X	X	X
Termination of Trial Medication	57							X									X
Conclusion of Study Participation	58														X		X
Signature Form	60	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant Medication Log	64	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Adverse Event Log	66		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Adverse Event Follow-up Log	68														X		X
Dose Management Log	70		X	X	X	X	X	X			X						
Study Drug Dispensing/Accountability Log	72		X	X	X	X	X	X			X						
Dose Management Log - Open Label Phase	74							X			X						
Continuation of Study Participation	76											X					

<sup>1</sup>If clinically indicated.  
<sup>2</sup>Two sets of field at screening (may do one at baseline) and at Month 6.  
(X's) - if needed.

<sup>3</sup>May be done at local lab.  
<sup>4</sup>If participating in OCT sub-study only.  
<sup>5</sup>If withdrawn prior to the Month 5 visit

Table e1.