Study Name, Arm	Who performs or administers the service? (PI, Co-Investigator, Study Coordinator, Nurse, etc.)	If at UCSF, list the address where the procedure/service is performed. REQUIRED	List the time it takes to perform each service. OPTIONAL - complete if CTBSC builds the budget	, and the second	Screening (Pre-Day of OTLX Randomizatio Treatment A 1,14,30,60,90,180,2					
List of Assessments	REQUIRED				LE 30 Days prior to OTLX	Baseline/Day 0		Post OTLX to hospital discharge	Day 14	
Inclusion/Exclusion Criteria					R					
Informed Consent					R	R				
Randomization Inclusion/Exclusion Criteria							R			
Medical History						S				
Physical Exam						S	S	S	S	
Height						S				
Weight						S	S	S	S	
Vital Signs						S	S	S	S	
HCG Pregnancy Test						S	R			
Hematology (local lab)					S	S	S	S	S	
Serum Chemistry (local lab)					S	S	S	S	S	
Biomarkers [d] (blood collected/shipped)										
Local Labs - AFP [k]										
Doppler Ultrasound [g]							R	R	R	
Concomitant Medication						R	R	R	R	
Adverse Events						R	R	R	R	
Serious Adverse Events						R	R	R	R	
Contrast imaging										
Blood draw					S	S	S	S	S	
		OPTIONA	L - complete if CTBSC builds	the budget> Misc. PI Time						
		OPTIONAL -	complete if CTBSC builds the	budget> Misc. CRC Time						

Treatment with drug										Follow Up				
70,360,450,5	40,630@630Days								EOT	Month 25 or 30 days after last				
Month 1	Month 2	Month 3	Month 6	Month 9	Month 12	Month 15	Month 18	Month 21	Month 24	study treatment	Month 27	Month 30	Month 36	
S			S		S				s	S			s	
			3		3				3	3			3	
S			S		S				S	S			S	
S			S		S				S	S			S	
R			R		R				R					
S	S	S	S	S	S	S	S	S	S	S	S	S	S	
S	S	S	S	R	S	S	S	S	S	S	S	S	S	
			R		R				R					
					S				S				S	
R														
R														
R	R	R	R	R	R	R	R	R	R	R	R	R	R	
					R				R					
S	S	S	R	S	R	S	S	S	R	S	S	S	S	