The Credentialing Process for the NSABP B-51 / RTOG 1304 Phase III Randomized Clinical Trial

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Purpose:

NSABP B-51/RTOG 1304 is a randomized phase clinical trial evaluating regional nodal (RN) radiothera (RT) in patients with positive axillary nodes bef neoadjuvant chemotherapy (NC) who convert to negative axillary nodes (ypN0) after NC. Patients follow lumpectomy are randomized to whole breast RT (A 1A) v breast and RN RT (Arm 2A); and post-mastecto patients are randomized to observation (Arm 1B) chestwall and RN RT (Arm 2B). This is the first mu institution group trial evaluating breast cancer RN requiring 3DCRT or IMRT treatment plans based on contouring with DVH plan evaluation. An institution m be credentialed to demonstrate that physics staff ha read the protocol, meet specific technological requirements, and generate RT plans that meet protoc defined RT dose volume constraints. The credential goal is to reduce protocol deviations and prov institutional feedback to correct unacceptable variation before patient enrollment.

Method:

Credentialing a Fa includes completing Questionnaire and developing 3DCRT and/or IN treatment plan for 3 CT benchmark cases for: Arm breast RT only; 2A – breast and RN RT; and 2B – p mastectomy chestwall and RN RT downloaded from IROC Houston's website. RN RT includes of coverage of supraclavicular, axillary, and inte mammary nodes in the first 3 intercostal spaces.



Figure 1: IROC Houston on-line Facility Questionnaire

IROC Houston reviews the benchmarks using MIM to verify that the dose to targets and constraints to organs at risk meet protocol-specified criteria. Credentialed institutions may then enroll patients. The first case enrolled on Arms 2A and 2B undergo pre-treatment review and are scored per protocol: variation acceptable or variation unacceptable.

NSABP B51 RTOG 1325	Note: Photon electron Mix composite plan Note: < 10 cc of composite plan (WB/CW + IMN elect) < 45 Gy Note: Press	(3) Variation Unacceptable
	CASE# Benchmark Maximum CASE# Dose to 95% of Lumpectomy PTV Eval Gy <= 35 Gy	dose within Ax PTV (1) Per Protocol (2) Variation Acceptable Gy
WHOLE BREAST CONCURRENT BO	OST TOTAL Dose to 90% of Lumpectomy PTV Eval > 57.5 Gy OST TOTAL > = 55.8 < 57.6 Gy	(3) Deviation Unacceptable ibed Dose 30 Gy, without Boost Field. IMN PTV
BREAST PTV EVAL PTV_WB_EVAL DOSE to 95% PTV_WB_EVAL > = 47.5 Gy (1) Per Protocol DOSE to 90% of PTV EVAL	Gy Volume of Lumpectomy PTV Eval receives > = 68.2 70.4 Gy >= 45 Gy <<<5%	(1) Per Protocol (2) Variation Acceptable (3) Deviation Unacceptable
> = 45 Gy (2) Accptable Variation < 45 Gy (3) Variation Unacceptable Note: Prescribed Dose 50 Gy, without Boost Field	Gy Score > 10 % (3) Deviation Unacceptable Note: Prescribed Note: Prescribed Boost Dose 62 64Gy Maximum dose within Lumpectomy PTV Eval C= 35 Gy Maximum dose within Lumpectomy PTV Eval C= 35 Gy	bed Dose 30 Gy, without Boost Field. ose within IMN PTV (1) Per Protocol (2) Variation Acceptable Gy
Volume of PTV_WB_EVAL receives > = 62 64 Gy <= 30%	% 71.3 73.6 Gy (1) Per protocol 33 - 37.3 Gy 71.3 -74.4 73.6 -76.8 Gy (2) Variation Acceptable Gy Score > 57.3 Gy % Score > 74.4 > 76.8 Gy (3) Deviation Unacceptable Note: Prescribed Boost Dose 62 64Gy Note: Prescribed Boost Dose 62 64Gy	(3) Deviation Unacceptable Gy
Note:boost prescribed dose 62 64 Gy Dose to 50% of PTV_WB_EVAL	REGIONAL NODES REGIONAL NODES Supraclavicu-lar (SCL) PTV SCL PTV Normal Its Volume of Volume of	ung Dose LUNG_IPSI
54 - 56 Gy (2) Variation Acceptable > 56 Gy (3) Deviation Unacceptable Note: Prescribed Dose 30 Gy, with Boost Field	Gy Score > = 47.5 Gy (1) Per Protocol Gy Volume of (= 30%) DOSE to 90 % of PTV SCL 00 Score 30 - 35 % 30 - 35 % 30 - 35 % > = 45 Gy (2) Accptable Variation Gy Score > 35%	(1) Per protocol (2) Variation acceptable (3) Deviation Unacceptable
Maximum dose within PTV_WB_EVAL <= 57.5 Gy (1) Per Protocol 57.5 - 60 Gy (2) Variation Acceptable <= 60 Over (2) Pariation Acceptable	< 45 Gy	LUNG_IPSI receives > = 10 Gy (1) Per protocol (2) Variation acceptable % (3) Deviction Leasentable
Note: Prescribed Dose 50 Gy, without Boost Field. Note: All Photons.	See page 64: Review on the composite plan (WB /CW + SCL) <= 55 Gy (1) Per Protocol <th< th=""> <th< th=""> <</th<></th<>	(1) Per protocol
Maximum dose within Breast PTV_WB_EVAL <= 62.5 Gy	Axillary (Ax) PTV Ax PTV DOSE to 95% of PTV Axilla Gy > = 47.5 Gy (1) Per Protocol Controlate	(3) Deviation Unacceptable
> 62.5 Gy for > 10 cc Note: Prescribed Dose 50 Gy, without Boost Field.	Gy Score DOSE to 90 % of PTV Ax Dose to 90 % of PTV Ax > = 45 Gy (2) Accptable Variation Gy Score Volume of Review on the <= 45 Gy	LUNG_CNTR receives > = 5 Gy (1) Per protocol
Figure 2. Eve	mnla of the Doce Volume And	alveie (D\/A)
for evaluation	of treatment plans	aiy 3i (DVA)
	or troutmont plano.	
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	800y 53.20 0y 50.00y 50.00y 50.00y 50.00y 50.00y 00.00y 50.00y 50.00y	
re Re		
	Figure 3: Benchmark for	
	Figure 3: Benchmark for Arm 1/1A	
	Figure 3: Benchmark for Arm 1/1A	-33 mm
	Figure 3: Benchmark for Arm 1/1A	Classification of the second secon
	Figure 3: Benchmark for Arm 1/1A	-J3 mm
	Figure 3: Benchmark for Arm 1/1A	era c.a.
	Figure 3: Benchmark for Arm 1/1A	arr CC
	Figure 3: Benchmark for Arm 1/1A	
	Figure 3: Benchmark for Arm 1/1A	-37 ms
	Figure 3: Benchmark for Arm 1/1A	2 an C.
	Figure 3: Benchmark for Arm 1/1A	a m tr
	Figure 3: Benchmark for Arm 1/1A	

Figure 5: Benchmark for Arm 2/2B

Figure 4: Benchmark for

Arm 2/2A

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Results:

NSABP B-51/ RTOG 1304 opened August 22, 2013 with a targeted accrual of 1,601. 213 institutions have initiated the credentialing process. 202 that have submitted benchmarks for review with 2% failed and never resubmitted. Credentialed techniques are 7% IMRT only, 52% 3DCRT only, and 41% 3DCRT and IMRT. Benchmark initial failure rates requiring resubmission are: 8% failed the benchmark for breast RT only (1A); 10% failed 2B post-mastectomy chestwall and RN RT; and 34% failed 2A breast and RN RT at least once before being credentialed. 9% of the institutions failed 2A twice and 3 failed three or more times and 9% failed 2A when planned using 3D and IMRT at the same institution. 199 are credentialed to enter patients. 19 enrolled cases have had pretreatment reviews and 2 scored "unacceptable" with re-submission for re-review due to target volume contouring.

The following are the most common areas of failure for the 1A :

- Lung_IPSI (Lung IPSI re'c 20Gy)
- PTV_WB_EVAL (Dose to 50% of PTV WB)
- PTV EVAL BREAST (Volume of PTV WB EVAL rec'd 62 Gy)

The following are the most common areas of failure for the 2A :

- PTV_Axilla (Dose to 95%)
- PTV_Axilla (Max point dose w/in PTV_Axilla)
- PTV_EVAL_Breast (Max dose w/in PTV WB)
- Lung_IPSI (Lung IPSI re'c 20Gy)
- PTV_EVAL_BREAST (Dose to 50% of PTV WB)
- PTV_EVAL BREAST (Volume of PTV WB EVAL rec'd 62 Gy)

The following are the most common areas of failure for the 2B :

- PTV_EVAL_CHSTWLL (Dose to 95%)
- PTV SCL (Dose to 95%)

Conclusions:

NSABP B-51/ RTOG 1304 credentialing prepares RT delivery to meet institutions for protocol requirements. This revealed Arm 2A, breast RT and RN RT has required resubmission most for institutions to meet protocol guidelines.

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