

Gynecologic Cancer InterGroup
Cervix Cancer Research Network

GYNECOLOGIC
CANCER INTERGROUP

An Organization of International Cooperative
Groups for Clinical Trials in Gynecologic Cancers

Welcome to TACO!



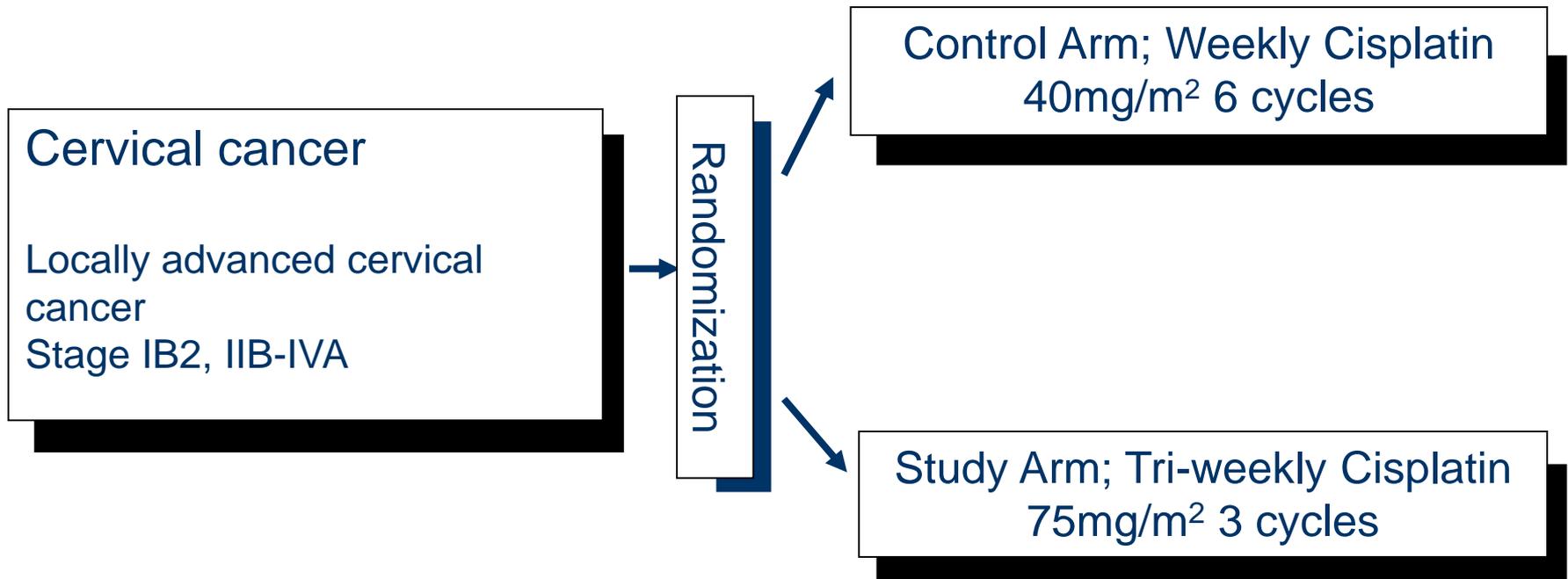
GCIG/KGOG1027/TGCS2012: Randomized Phase III Clinical
Trial Comparing Weekly vs Tri-weekly Cisplatin Based
Concurrent Chemoradiation in Locally Advanced Cervical
Cancer

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Cervix Cancer Education Symposium, February 2018

TACO

(Tri-weekly Administration of Cisplatin in Locally Advanced Cervical Cancer)



Chemoradiation

- 5 RCTs; 30-50% improvement of survival
-

	Regimen	Cisplatin	No. of cycle
GOG 85	FP	50 mg/m ² /3wk	2
GOG120	W-P	40 mg/m ² /wk	6
	FP	50 mg/m ² /4wk	2
GOG 123	W-P	40 mg/m ² /wk	6
SWOG 8797	FP	70 mg/m ² /3wk	4
RTOG 90-01	FP	75 mg/m ² /3wk	3

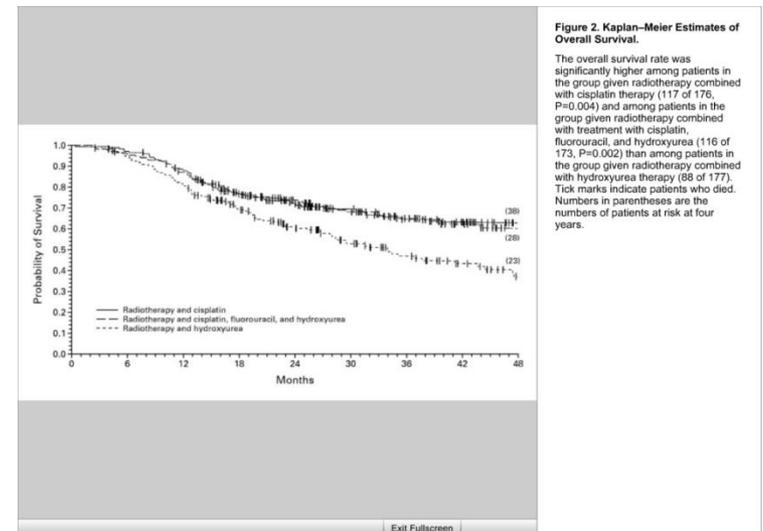
Victory of Weekly Cisplatin 40mg/m²

- Weekly cisplatin 40 mg/m²
 - Favored because convenient, equally efficacious, less toxic

- GOG 120

Arm 1; W-cis #6 ^{vs} FP #3

Comparable outcome



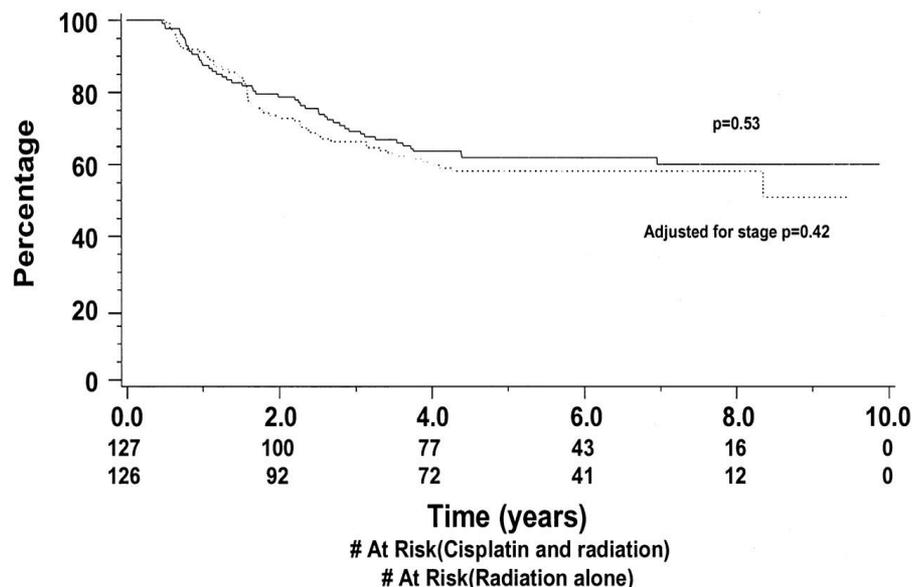
NCIC trial

- Sixth RTC: NCI Canada, 2002**

259 patients, Stage IB to IVA, > 5cm, or pelvic lymph node (+)

W-Cisplatin 40 mg/m² vs RT only

- NO significant difference in PFS and 5YSR



Pearcey R et al. JCO 2002;20:966-972



Is Weekly-cisplatin an optimal dose ?

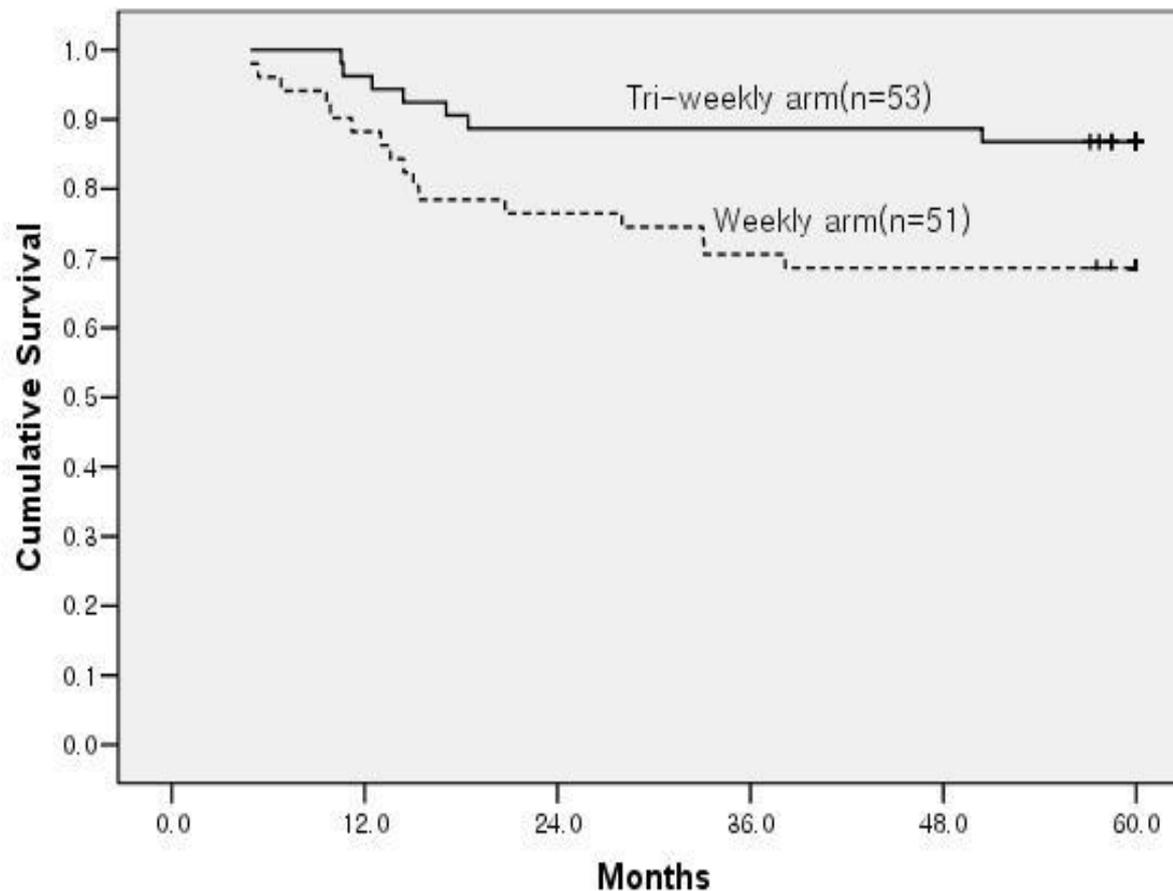
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Ryu et al., IJROB 2011

5YSR ; 88% vs 66% ; HR 0.375 , 95% CI(0.154-0.914) p=0.03



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Tri-weekly CRT Toxicity (Ryu et al., IJROBP 2011)

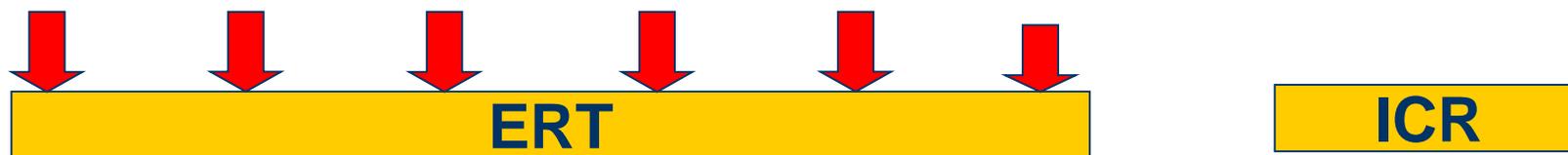
	Weekly(%) (n=51)		Tri-weekly(%) (n=53)		P-value
	Grade 1-2	Grade 3-4	Grade1-2	Grade3-4	
Neutropenia	20(38.5)	21(40.4)	23(43.4)	12(22.6)	P < 0.05
Thrombocytopenia	13(25.0)	5(9.6)	3(5.7)	3(5.7)	
Nausea	43(82.7)	3(5.8)	46(86.8)	2(3.8)	
Vomiting	13(25.0)	0	11(20.8)	0	
Nephrotoxicity	8(15.4)	0	15(28.3)	1(1.8)	
Neurosensory	5(9.6)	0	2(3.8)	0	
Alopecia	13(25.0)	0	17(32.1))	0	



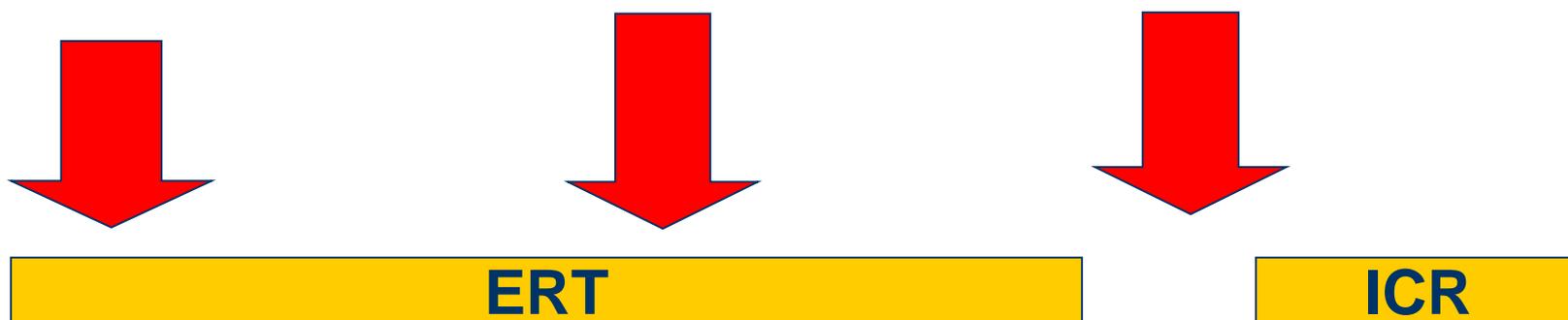
What we want to prove is...

- Hypothesis
 - Peak concentration > Not exposure time
 - Synergy of chemoradiation
 - Eliminate the micrometastasis

Weekly cisplatin



Tri-weekly cisplatin



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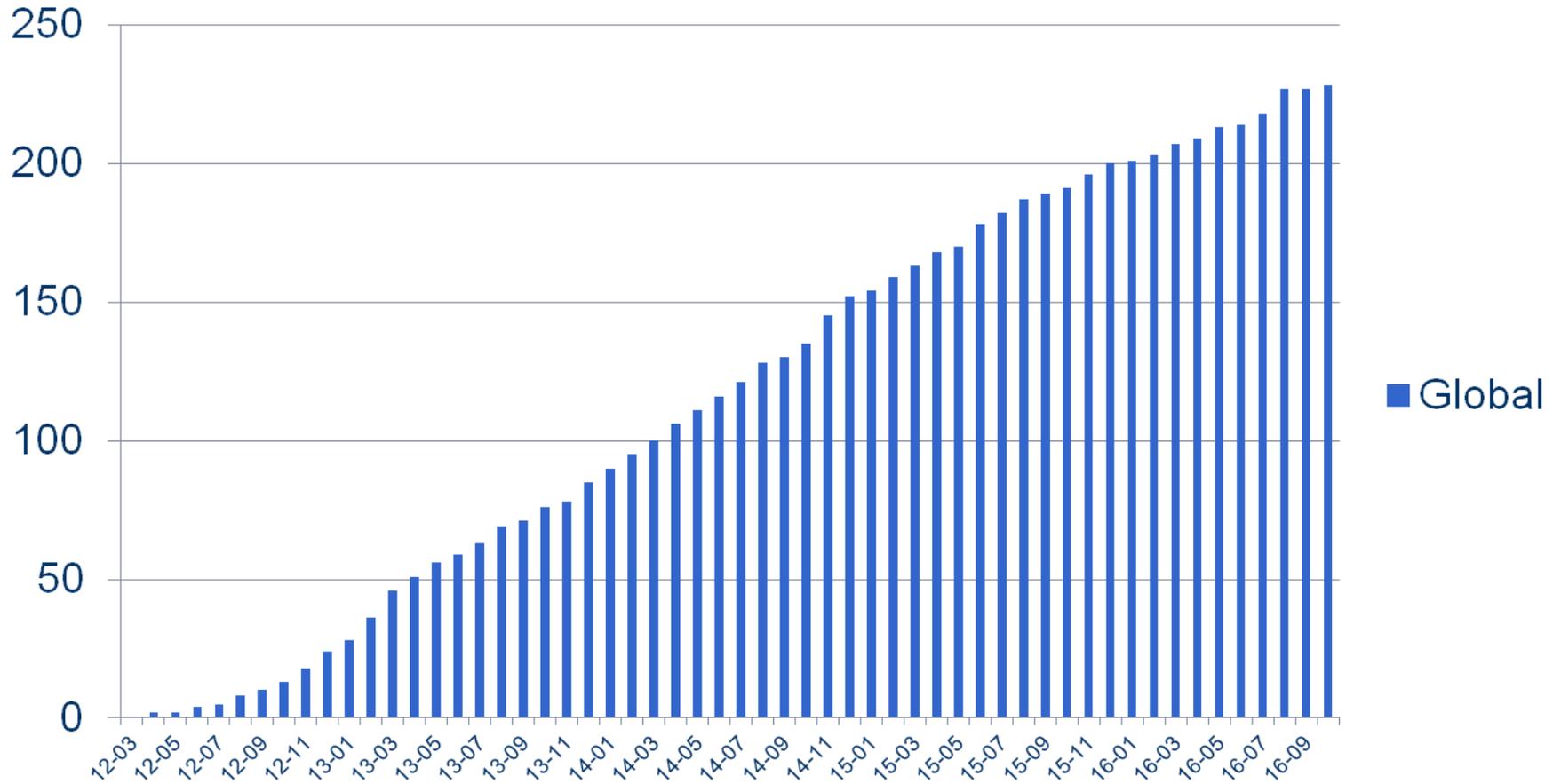


- Statistics (revised)
 - Increase of 5YSR: 65-> 77%
 - 80% power, Two-sided test type I error=5%
 - Expected HR=0.607 (39% reduction)
 - Accrual time; 48 months
 - 168/arm , 10% loss,
 - Total; 374pts (Current; 260cases)

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Accrual of TACO

Global





TACO Monitoring

- QC monitoring/Audit
- Data Management/e-Velos
- RT QA

QC monitoring in Ramathibodi Hospital





RT-QA (GCIG-CCRN)

- Pretreatment AP/Lat portal film review
 - within 24 hours
- Post treatment RT review
 - Biennial meeting
 - Acceptable/Deviation acceptable/Unacceptable

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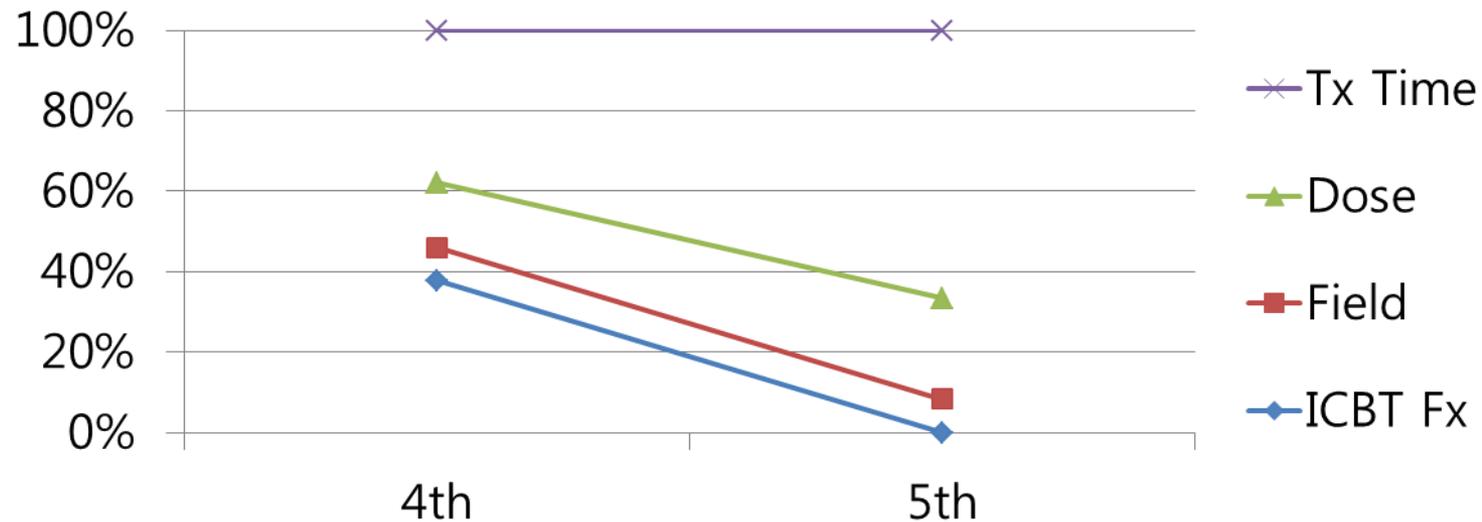


RT QA in TACO



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RT QA in TACO

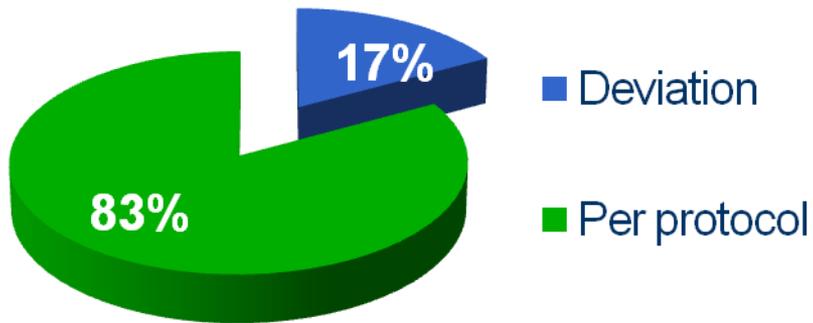


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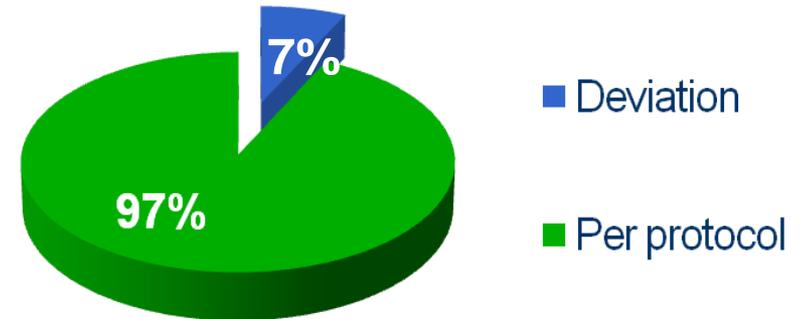


1 st QC Deviation	2 nd QC Deviation
17%	7%

1st QC Monitoring



2nd QC Monitoring



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TACO GONNA CHANGE STANDARD!

KGOG 12 sites

Thailand 1 site

Vietnam 1 site

China 2 sites



Tri-weekly cisplatin
may be better than
current standard
weekly cisplatin-
CRT.

Thank you for your attention.