### Test Results Module - Pharmacokinetics Overview

				PK Templates				1					
			ATV_EFV			- Add New							<
Name		ATV_EFV	*		F				PK C	ontrol Lots		2	
- Analytes	S				F				00	Calibrator			
Analyt	e	Unit	Lower Limit	Upper Limit			Control_ABC_	_123	0.60	Calibrator	*	Add New.	
ATV		▼ NG/ML	<ul><li>✓</li><li>200</li></ul>	2,500		Lot Number	Control_ABC_123	*			10 - 312 - 10 - 3		
EFV		▼ NG/ML	▼ 200	2,500	8	Creation Date	01/Apr/2022	*					
				Save Template Delete Template		Expiration Date	01/Apr/2023	*		Create	Pending Test Res	ults	3
				Save template Delete template		Storage Temperature (C)	Θ	*	General Results				$\checkmark$
						Derivative/Matrix Type	PL2	*	Test Name	PK Assay			
	PK	Assa	y Workfl	low		Controls			Run Date	dd/MMM/yyyy	-		
	1.	Build te	emplate and	l define analvtes					Assay Name		*		
	2.	Build C	C and Calib	rator lots		Control	Custom Name		Run Type		*		
	3.	Create	a run in the	Assav module		LQC			Detect Platform Analytes		*		Add Analyte
	4.	Upload	l results in th	ne Results tab		MOC				Analyte	Unit	Lower Li	imit
	5.	Chart a	ggregated C	)C values		ingo			Control Lots	<b></b>			Add Control Lot
						HQC			Commente	Lot Number	Calibrator	Creation Date	Expirat
									Comments				(4)
		Inter-Day A	Average Back Calculated C	alibration Standards		Unmatched Results from	File						Upload File
		Accuracy a	and Precision for Quality Con	ntrols		File Id 🔺 Item Nam	e Analyte	Un	it Lov	ver Limit	Upper Limi	t R	esult
		Stability	ce Chart for Quality Controls	NICE SAUTHORS					Complete Save Close	se			
		Partial Volu Matrix Reco	mes Precision and Accuracy overy Effects (Template 1)	y (Template)									
		Matrix Reco	overy Effects (Template 2) overy Effects (Template 3)										
		Inter-Day	y Average Back Calcul	lated Calibration Standards 🔽									
		PDF (*.p	Generate Report	<b>~</b>									



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### PK Module—Template Design

Hover over "Test Results" select "PK Templates". En	in the navigation ter a unique As	on menu to e say Name in t	xpand the list, the "Name" field.	PK Templates		Test Results - Test Results PK Control Lots	Data		
	Name — Analytes ————		*		Add New	PK Control Cha PK Templates	Add Ana	alyte	
	Analyte	Unit	Lower Limit Upper L	imit					
			Save	Template Delete Te	emplate			k "Add Anal erimental d	yte" for ea lesign.
			Analytes       Analyte     Unit       Analyte     Image: Comparison of the second se	Unit NG/ML	Lower Limit Upper L Lower Limit 200	.imit Upper Limit 2, 500		For each A Sele Sele Sele NOT be a run	Analyte : ct an Analy ct the Unit the Lower E: the upp djusted fo setup if ne
				Analyte	e Unit	Lo	ower Limit	Upper Limit	
3				ATV	▼ NG/ML	<b>▼</b> 2	200	2,500	
Click the "Save T	emplate" at the	e bottom of th	ne		-	•			
window. The new	w template is no	ow ready to u	Se. PK Templates		Analyte	Unit	Lower	Limit Upper	Limit
					ATV	NG/ML	✓ 200	2,50	9
Name	ATV FFV	ATV_EFV *		-	EFV	NG/ML	· 200	2,50	Ð
Analytes	[::::===:::				<u>-</u>				
Stort2 - Bores						Add Analyte			
Analyte	Unit	Lower Limit	Upper Limit						
ATV	▼ NG/ML	▼ 200	2,500			Delete			
EFV	▼ NG/ML	200	2,500			Delete			
			Save Template Delete Tem	plate					



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h Analyte : elect an Analyte elect the Unit of measurement et the Lower and Upper Limits OTE: the upper and lower limits can e adjusted for individual runs during in setup if necessary.



2

### PK Module—Calibrators and QC Lot Entry

Test Result         Test Result         PK Control         PK Control         PK Templa	s Lots Charting tes	Hover ove the list, se Select QC	er "Test Re elect "PK ( or Calibra	esults" in t Control Lo ator from	the navigation ots". the radio but PK Control Lots	n menu to tons OQC	expand 1 Calibrator Calibrator	<ul> <li>For the QC or Calibrator lot:</li> <li>Enter a unique name or number in the "Lot Number" field</li> <li>Set the Creation Date and Expiration Date using the drop down calendars</li> <li>Enter the Storage Temp</li> <li>Select the Derivative/Matrix Type from the drop down menu</li> </ul>
Creation Date Expiration Date Storage Temperature Derivative/Matrix Ty Controls	dd/M dd/M e (C) 0 pe	ММ/уууу ММ/уууу	× *		Lot Number Creation Date Expiration Date Storage Tempe Derivative/Mate	e erature (C) rix Type	LOT123 14/Apr/2022 14/Apr/2023 0 PL2	<ul> <li>Click "Add New" for each Control or Calibrator For each:         <ul> <li>Define the Control or Calibrator from the dropdown</li> <li>Define a Custom Name (optional)</li> </ul> </li> </ul>
<b>Control</b> Analytes	Custo	om Name						Add New     MQC
Analyte	Unit		Target	+/-%	Target Min	Target Max		Click "Add New" to add an Analyte.
Analyt	Click the "Save Lot" at the bottom of The Calibrator or Control Lot is now Analytes Unit Target 3TC MG/ML 300					5 V. Target Min	Target Max	<ul> <li>For each Analyte :</li> <li>Select an Analyte</li> <li>Select the Unit of measurement</li> <li>Set the Target and Variance (+/- %), the minimum and maximum are automatically calculated</li> <li>NOTE: Target and Variance (+/- %) can be adjusted on individual runs or Controls and Calibrators during run setup if necessary.</li> </ul>
310		NG/ML		300	10	200	343	Delete









## PK Module—Pending Test Results

[.	Hover over "Test Results	s" in the navigation							A	dd PK Control Lot	Now Hole Com
n	menu to expand the list	, select "Test Results".				Create Pend	ing Test Results	Lot Number Creation Date	dd/MMM/yyyy *	* *	Mare Copy
Test Results V	select "Add Pending Res	p down menu, and sults". Select "PK	General	Results			Add PK Analyte	Expiration Date Storage Temperature (C Derivative/Matrix Type	dd/MMM/yyyy * C) 0 *	* *	
Test Results A	Assay" from the Test Na	me drop down menu.	Test Name	Results	PKAssay	Analyte		Controls	Add PK Template		Add Nev
PK Control Lots	-		Run Date		dd/MMM/yyyy	- Lower Limit				T Add New	
PK Control Chartin	Select Test		Data Transfe	r Tech		Upper Limit	Analytes				Add New
PK Templates			Assay Name			*	Analyte Un	it	Lower Limit Upper Limit		idd Analyte
Test Name	Abbott RealTime HIV-1 RNA	*	Detect Platfo	rm		*			Add Close		
	COBAS TaqMan HCV		Analytes							Add Ar	nalyte 💌
	COBAS TaqMan HIV-1 Qual PK Assay				Analyte	Unit	Lower Limit		Upper Limit		
L			Control Lots		Let Number Calibre	Creation Data	Eunivation Data	Storage	e Deri	Add Co	introl Lot
			Commonto		Lot Number Calibra	Creation Date	Expiration Date	Temper	rature (C) Type	•	
	Test Name	PK Assay	Comments								
	Run Date	22/Apr/2022 👻				Complete	Save				
	Assav Name	ABC *								(3)	
2	Run Type	Routine ×			Add Analyt	es and Contro vidually or fro	ols. Analytes a	nd Cont	rols can be		
Fill out the Run D	Details:	Mass spectrometry (MS) 💌 *		Analytes			in preset tem				tid Analyte
<ul> <li>Define "Run</li> </ul>	n Date" using the drop d	own calendar			Analyte	Unit	Low	ver Limit	Upper I	Limit	
Define "Data	a Transfer Tech" initials				ATV	NG/ML	200	)	2500		Edit
Define "Assa	<ul> <li>Define "Assay Name"</li> <li>Select "Run Type" from the drop down menu</li> </ul>				EFV	NG/ML	200	i	2500		Edit
<ul> <li>Select "Ruh</li> <li>Select "Doto</li> </ul>	<ul> <li>Select "Run Type" from the drop down menu</li> <li>Select "Detection Platform" from the drop down menu</li> </ul>				ts				1	Ad	d Control Lot
- Select Dele		ic drop down menu			Lot Number	Calibrator Crea	tion Date Expirat	ion Date	Storage Temperature (C)	Derivative/Matrix Type	
					Control_ABC_1	23 01/A	pr/2022 01/Apr	/2023	0	PL2	Remove







## PK Module—Pending Test Results

		E	dit Pending Test Results							ing Edit 💌
General       Results         Run Id       18         Test Name       PK Assay         Status       Pending         Run Date       22/Apr/2022         Data Transfer Tech       ABC         Assay Name       TEST					al" 1	Edit Pending Test I	Experin in the " lots on	nental cor Controls" the "Gene	ntrols will grid from eral" tab.	2   be auto-populated any added control     Add Control     Add Control     View History   Pending Test Results Report   1D Barcodes Report   2D Barcodes Report   We d     View History
Run Type	Routine	*	LQC		Cus	tom Name		Calib	orator	Edit
Detect Platform	Mass spectro	metry (MS) 👻 *	MQC							Edit
Analytes	1		нос							Edit
	Analyte ATV EFV	Unit NG/ML NG/ML	200 200	Specimens						Add specimens for evaluation and define their
Control Lots	1			Dilution	Project	ID1	Global Specimen	ID	Other Specin	dilutions in the "Specimens" grid. For example, a
	Lot Number	Calibrator Creatio	n Date Expiration	1	FRONTIER	123ABC456	9999-0002TF00-	001		10:1 dilution would be listed as "10".
Commente	Control_ABC_	123 01/Apr	72022 01/Apr/2	1	FRONTIER	123ABC456	9999-0002TF00-	002		Note: The Dilution value is informational and will not
Comments		Results Specify limit	ts per specimen					Clear Results	For Analyte	be used to calculate or adjust the final results.
		Name	Analy	yte Unit	Target	+/-%	Lower Limit	Upper Limit	Result	
		MQC	ATV	NG/ML	▼ 8000	15	6800	9200		
		MQC	EFV	NG/ML	▼ 8000	15	6800	9200	The "Resu	Its" grid will be populated with analyte rows
		HQC	ATV	NG/ML	▼ 12000	15	10200	13800	for each co	ontrol and selected specimen. The "Result"
		HQC	EFV	NG/ML	- 12000		10200	13800		in remain empty until results me is uploaded.
Click "Save" in c Clicking "Close"	rder to sa will not sa	ve all updates ave any updat	made to the es.	experimenta	al design.	5	200 <b>6</b> 200 200	The "Pend	ding Test R	Results" report will be available after saving the run setu
Unmatched Results from File	Analyte	Unit	Lower Limit	Upper Lim	it Resu	Upload File	200	This repo	rt can be g	enerated and printed to aid in setting up the physical ru
		Complete	Save Close							g Edit View History Dending Test Results Percent







Delete

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## PK Module—Completing Results

Results								Unmatched Results	s from File						Uplo	ad File	
Specify limits per specir	nen					Clear Results	For Analyte	File Id 🔺 Iten	n Name	Analyte	Unit	Lo	wer Limit	Upper Limit	Result		
Name	Analyte	Unit	Target	+/-%	Lower Lim	nit Upper Limit	Result				Comp	lete Save Cl	ose				
MQC	ATV	NG/ML	- 8000	15	6800	9200			ad a resu	lts file on		av is con	nleted	Results e	ntered to I	DMS	T
мдс	EFV	NG/ML	▼ 8000	15	6800	9200		shou	ild he the	final calc	ulater	ay is con I result a	nd must	already a	count for	dilutions	
нос	ATV	NG/ML	▼ 12000	15	10200	13800		51100					nu must	. all cauy a		unutions.	
нос	EFV	NG/ML	▼ 12000	15	10200	13800											
9999-0002TF00-001	ATV	NG/ML	-		200	2500		Results v	vill auto-r	natch as l	ong as	s sample	names	match the	names of	the sampl	es in the r
9999-0002TF00-001	EFV	NG/ML	-		200	2500	Results	I file. Auto	o-matche	s can be r	nade i	using Glo	bal Spe	cimen ID, I	Participant	t ID, or Oth	ier Specin
9999-0002TF00-002	ATV	NG/ML	-		200	2500	Specify I	nits per specimen							Clear	Results For Analyte	
9999-0002TE00-002	FEV	NG/ML	-		200	2500	Name		Analyte	Unit		Target	+/-%	Lower Limit	Upper Limit	Result	
							LQC		ATV	NG/ML	•	300	15	255	345	295	
							LQC		EFV	NG/ML	•	300	15	255	345	290	
f the naming o	conventi	ons do	not align	, individu	ual sampl	le 🤦	MQC		ATV	NG/ML	-	8000	15	6800	9200	7980	
esults can be	dragged	from th	ne "Unma	atched Re	esults" gr	rid 💙	MQC		EFV	NG/ML	•	8000	15	6800	9200	7990	
ind dropped to	o match	the res	ults to th	e approp	oriate san	nples.	нос		ATV	NG/ML	•	12000	15	10200	13800	11090	
						B800	нос		EFV	NG/ML	•	12000	15	10200	13800	11080	
нос	ATV	/	NG/ML	- 12000	9 15	1020	0 10	1103	0								_
нос	EF	/	NG/ML	- 12000	9 15	1020	0 13	300 1108	0								
9999-0002TF00-001	ATV	/	NG/ML	*		200	25	90 1234									
9999-0002TF00-001	EF\	/	NG/ML	- 6		200	25	90		100 (10)							
9999-0002TF00-002	AT	/	NG/ML	*	C 1					NG/ML	*	8000	15	680	92	200	7990
9999-0002TF00-002	EF	/	NG/ML	-	Result. 0545		1	1	-1	NG/ML	-	12000	15	102	00 13	3800	11090
						1 1100		L1	·]	NG/ML	*	12000	15	102	00 13	3800	11080
					$\frown$	9999-0	002TF00-00	1 AT	v	NG/ML	*	1		200	25	500	1234
					— ( <b>4</b> )		0007500 00	4				1		200	21	-00	6542
Click "Save" in	order to	o save al	ll update	d test res	sults.	9999-0	0021F00-00		v	NG7 ML				200	23	500	0543
Click "Complet	e" to fin	alize re	sults of th	ne run.		9999-0	002TF00-00	2 AT	V	NG/ML	-			200	25	500	4321
						9999-0	002TF00-00	2 EF	V	NG/ML	-			200	25	500	3456
IOTE- Result c	ensorin	g is com	pleted d	uring the	e												
Review Results	steps o	n the ne	ext slides.												1. 6		
Unmatched Results from	File						NOTE-	If a result v	vas not ol	otained fo	r a spe	ecific spe	ecimen l	eave the re	esult field	for that ro	w Blank / I
File Id 🔺 Item Nam	e	Analyte	Unit		Lower Limit	Upper Lin	Leavin	g a result B	lank / Nu	ll may be	neces	sary in s	cenarios	such as a	template i	ncluding a	in analyte
							1,1100,000	t tostad for	acampl	o on tho r	un hai	ing incu	fficients	volumo a	an issup i	nintornrot	ing the fir
					24 14			i lesteu ioi	, a sampt	eontilei	unnav	ving insu	melent	volume, or	anissuen	ninterpre	ing the m



Upload File
s entered to LDMS y account for dilutions.
2 the names of the samples in the results D, Participant ID, or Other Specimen ID.
Clear Results For Analyte



## PK Module—Reviewing Results

									Edit Completed Te	st Results			7			
Once Results h	ave been "Co	ompleted" t	hey can be	now be "Revie	ewed"	General	Control Results	Specimen Results	s							
	Edit C	ompleted Test Resul	s		1	Controls Control Nar	me	Custom Na	ame	Calibrator	Analyte Result System	User				
						LQC					ATV 295 Censor	rs Censor				
General Control Res	ults Specimen Resul	ts			1	LQC					EFV 290	-				
Run Id	18					MQC			General Contr	ol Results Specimen	Results					
Test Name	PK Assay						)		Specimens							
Status	Completed	Fill out the	Review Det	ails:					Project	ID1	Global Specimen ID	Dilution	Analyte	Result	System	User Censor
Run Date	22/Apr/2022	Defin	e "Review D	ate" using the	e drop down cal	endar	selected control		FRONTIER	123ABC456	9999-0002TF00-001	1	ATV	1234	Censors	Censor
Data Transfer Tech	ABC	<ul> <li>Defin</li> <li>Defin</li> </ul>	e "Reviewer	finitials Commonte"					FRONTIER	123ABC456	9999-0002TF00-001	1	EFV	6543	A	<b>•</b>
Assay Name	TEST	• Delin	e Reviewer	comments		.			FRONTIER	123ABC456	9999-0002TF00-002	1	ATV	4321	A	-
Run Type	Routine	Review Date	e	26/Apr/2022	-				FRONTIER	123ABC456	9999-0002TF00-002	1	EFV	3456	A	3
Detect Platform	Mass spectrom	Reviewer In	itials	ABC			Deeu	lto for Co	امعدما معط	Cracinacia			Caraa		a a la	
Analytes	Analyte		nuis	ABC			Resu	its for Co	ntrois and	Specimen	s can be assig	ned a	Censo w the	or to ea	acn	
	ATV	Reviewer C	omments	No Comment				i ot anu ea	ach specin	ien evaluat	led by the Use		n the	Syster	11 (5).	
						,		A <sup>S</sup> - Inval	lid Greater	r than the i	ipper limit di	ilute a	nd ren	eat		
Control Lots	Lot Number		<ul> <li>B<sup>US</sup>- Below Quantifiable Limit or No Peak</li> </ul>							ia rep	cut					
	Control_ABC_1	.23 0:	1/Apr/2022	01/Apr/2023			•	D <sup>U</sup> - Drug	g not requi	red to be a	ssaved		U	lser		
Comments							•	F <sup>s</sup> - Faile	ed i		<b>,</b>		C	ensor		
Completed By	lenzo@fstrf.org						•	H <sup>s</sup> - Una	cceptable I	HQC						
Completion Date	26/Apr/2022 15:49	i i					•	I <sup>s</sup> - Unac	ceptable H	IQC						
Review Date	dd/MMM/yyyy	*			4		•	L <sup>S</sup> - Lowe	er limit adj	usted up fo	or this run		C	C		
Reviewer Initials			Click "S	ave" in order	to save all		•	M <sup>s</sup> - Una	cceptable	MQC			F	2		
Reviewer Comments			updated	test results.	Click		•	N <sup>U</sup> - Not	Detected				0	)		
L			Contraction (Contraction)	" to finalize re	eviewing		•	0 <sup>U</sup> - QC o	out of rang	e, dilute ar	nd repeat		>	<	-	
	Revie	w Save Close	the resu	llts of the run.			•	P <sup>U</sup> - Not <i>i</i>	Able to Inte	erpret Resi	ult		Z	2		
							•	Q <sup>s</sup> - Una	cceptable I	LQC/LQC1	/LQC2		E	3		
					5		•	R <sup>s</sup> - Repe	eat (with L	system cer	nsor only)				1	
	NOTE- Resu	lt censoring	can only be	completed d	uring the		•	S <sup>o</sup> - Quai	ntity not su	ufficient						
	Review Resu	ults steps. If	Review has	been comple	ted and		•	U <sup>2</sup> - Sam	iple Diluted							
	censors still	need to be	applied, the	run will need	to be		•	X° - Perl	ab, sample	e must be r	epeated					
reset to "Pending"							•	Z° - NO R	kesult, Lab	issue						



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specimen ID	Dilution	Analyte	Result	System Censors	User Censor
002TF00-001	1	ΑΤ٧	1234		-
002TF00-001	1	EFV	6543	A	-
002TF00-002	1	ATV	4321	А	-
002TF00-002	1	EFV	3456	A /	





### PK Module—Control Charting

Test Results 🔻									
Test Results			The PK Control Charting m	nodule is used to	o create CPQA required reports by pulling data from multiple runs to				
PK Control Lots			track the performance of C Analyte, Lot Type, and Lot	QC Lots. Some re Number can be	eports are empty templates where data is entered manually. Only one set in the search criteria. Multiple runs can be included in the report.				
PK Control Charting	Hover over "Test R	Results" in the navigation mo select "PK Control Charting	enu ""	_					
PK Templates			PK Control Charting	Analyte	STC ~ ~ ~				
				Lot Numbe	er BTC *				
	Analyte	•	*	Min Run D	ate 04/Jan/2022				
	Lot Type	QC Calibrator		Max Run D	Date 26/Mar/2022 3				
	Lot Number		*	8	To search for runs:				
	Min Run Date	dd/MMM/yyyy			<ul> <li>Select Analyte</li> <li>Select Lot Type</li> </ul>				
	Max Run Date	dd/MMM/yyyy			Select Lot Number				
	Selected	Run Id Assay Name	Run Type	Run Date	Limit the results by date range using the     Min and Max Run Date fields				
Selected	Ru	n Id Assav Name	Run Type	Run Date	Tech Initials Status				
		209	Routine	13/Jan/2022	ACB Completed				
Runs that match	search criteria appea	ar							
runs to be inclue	ded in the report.	4							
L	•			h	nter-Day Average Back Calculated Calibration Standards				
	(5)				Accuracy and Precision for Quality Controls				
	То в	generate a report:		S	Stability				
	•	Select the report type by	using the "Report Type" drop dowr	n menu	Partial Volumes Precision and Accuracy (Template)				
	•	Select the file type by usir	ng the "File Type" drop down menu	J N	Matrix Recovery Effects (Template 1)				
	•	Click "Generate Report"		N	Matrix Recovery Effects (Template 2)				
	0 - 0 of 0 results			N	Matrix Recovery Effects (Template 3)				
		Report Type	Inter-Day Average Back Calculat	I ted Calib	Inter-Day Average Back Calculated Calibration Standards 🔽				
		File Type	PDF (*.pdf)	P	PDF (*.pdf)				
		event SALte 🕶 Paren	Generate Report		Generate Report				
l									





# PK Module—Reports

Additional PK reports can be generated from Standard Reports inside of the Reports Module:       PK         Pharmacology Drug Count       Report Categories         Pharmacology Drug List       Report         Pharmacology Proficiency Results       Reports          PK Drug Limits by Run       Reports          PK SUlmmary Report       Standard Reports         PK Summary with Assay Name       Custom Report Builder	Some PK reports can be generated from the dropdown menu inside of the Test Results Module: PK Assay Results Report Participant Report 1D & 2D Barcodes Report And More View History Reviewed Test Run F Participant Report 1D Barcodes Report 2D Barcodes Report Reset to Pending Delete	1         2D Barce           Searched on:         Searched on:           Global Spec ID         9999-0002TF0           WWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWW	de Report         Run ID = 18         OD1 FRONTIER STUDYABC 123ABC456 2021-08-04 2.00 Vst         IDBarcode Report         Searched on: Run ID = 18         OD2 ID Project ID2 ID1 Collection Date Other         9999-0002TF00-001 FRONTIER STUDYABC 123ABC456 2021-08-04       2021-08-04         WWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWW	<u>Pec ID</u> Vid       Vid Unit         2.00       Vst         2.00       Vst         2.00       Vst
PK Participant Report PK Summary Report PK Summary with Assay Name	Additional PK reports can be generated fro Standard Reports inside of the Reports Mo • Pharmacology Drug Count • Pharmacology Drug List • Pharmacology Proficiency Results • PK Drug Limits by Run • PK Participant Report • PK SUmmary Report • PK Summary with Assay Name	2 om dule: Reports T La Standard Report Custom Report E	Report Categories       PK         Report       Select a report         abels       Pharmacology         Builder       Pharmacology         PK       Provide the second seco	ports          rt <ul> <li>rt</li> <li>Drug Count</li> <li>Drug List</li> <li>Proficiency Results</li> <li>ts By Run</li> <li>nt Report</li> <li>eport</li> <li>ith Assay Name</li> </ul>



