

# Dalbavancin Population Pharmacokinetic Modeling and Target Attainment Analysis

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## Supplemental Material

### Structural Model

The structural model was explored using first-, second-, and third compartment models with zero-order input and first-order elimination. The conditional weighted residuals for the 1 (Run 101) and 2 (Run 102) compartment models showed positive bias (under prediction) as time increased. The three-compartment model (Run 103) reduced this bias and provided a significantly better fit than the two-compartment model, with a decrease in Objective Function Value (OFV) of 87 points as shown in **Supplementary Table S1**. These models incorporated IIV on V1, (CL, V2, and Q2 as independent random effects as in the previous popPK model.

Several models were tested for various structures of the random effects. A full block omega (on CL, V1, Q2, V2) improved the two-compartment model by 435 OFV points. Expanding the random effects to all parameters in the three-compartment model (Run 105) improved on the three-compartment model by 155 points, but resulted in high shrinkage for all but volume and clearance random effects. Removing a single random effect from the third-compartment did not improve the model, with removal of V3, 123 points worse (Run 106) and removal of Q3, 3 points worse (Run 107). Random effects on only CL and the three-compartmental volumes

(Run 108) was 11 points better than Run 107, and 8 points better than Run 105 with one and two fewer parameters respectively.

Analysis of the random effect correlation for Run 108 showed high correlation in CL, V1, and V2, with V3 being uncorrelated ( $\rho < 0.75$ ). Run 109 accounted for this correlation and reduced OFV by 368 points with three additional parameters. Run 110 explored correlation between CL and V1 only, resulting in a 125 point improvement vs Run 108. Run 111 added correlation of V2 and V3 on top of the model in Run 110 with an associated three point improvement on one additional parameter. Run 112 tested correlation just among the volumes and was 62 points better than Run 108. Run 113 tested a full correlation and resulted in a 412 point drop vs Run 108. Run 117 tested a full block matrix on the model of Run 103, finding a worse OFV than the full block model with V3 swapped for V2 (Run 113).

Accounting for correlation in all random effects (Run 114) improved the model greatly (412 points vs Run 103), but was not better than Run 113. Dropping V3 and Q3 random effects in the full block omega changed OFV by 105 (Run 115, worse) and -30 points (Run 116, better) respectively. Run 116, Run 113 and Run 114 had the lowest OFV values, but had some convergence problems that indicated over-parameterized omega matrices. Run 109 was only 44 points worse than the full block model for CL+V1+V2+V3 (Run 113), converged with no problems, was stable enough to succeed in the covariance estimate, and was supported by the random effects distribution from the diagonal omega (Run 108).

**Supplementary Table 1: Model Building Trail in the PopPK Structural Model**

Run	Based on	Description*	OFV	ΔOFV	Minimization Status	Covariance Step Status
101	0	1 cpt, Omega(CL, V)	19900.6		Successful	Successful
102	101	2 cpt, Omega(CL, V, Q2, V2)	16494.6	-3406.0	Successful	Successful
103	102	3 cpt, Omega(CL, V, Q2, V2)	16407.7	-86.9	Successful	Successful
104	102	2 cpt, Omega(CL + V + Q2 + V2)	16059.2	-435.4	Successful	Failed
105	103	3 cpt, Omega(CL, V, Q2, V2, Q3, V3)	16253.2	-154.5	Successful	Successful
106	105	3 cpt, Omega(CL, V, Q2, V2, Q3)	16375.9	122.7	Successful	Successful
107	105	3 cpt, Omega(CL, V, Q2, V2, V3)	16256.3	3.1	Successful	Successful
108	107	3 cpt, Omega(CL, V, V2, V3)	16245.7	-10.5	Successful	Successful
109	108	3 cpt, Omega(CL + V + V2, V3)	15877.4	-368.3	Successful	Successful
110	108	3 cpt, Omega(CL+V, V2, V3)	16120.5	-125.2	Successful	Successful
111	110	3 cpt, Omega(CL + V, V2 + V3)	16117.3	-3.3	Successful	Successful
112	108	3 cpt, Omega(CL, V1 + V2 + V3)	16183.7	-62.1	Successful	Successful
113	108	3 cpt, Omega(CL + V + V2 + V3)	15833.5	-412.2	Successful	Failed
114	104	3 cpt, Omega(CL + V + Q2 + V2 + Q3 + V3)	15852.4	-206.8	Successful	Failed
115	114	3 cpt, Omega(CL + V + Q2 + V2 + Q3)	15957.3	104.9	Failed	Failed

116	114	3 cpt, Omega(CL + V + Q2 + V2 + V3)	15822.4	-30.0	Successful	Failed
117	103	3 cpt, Omega(CL + V + Q2 + V2)	15996.9	-410.8	Successful	Failed

ΔOFV=change in objective function value; 3 cpt= three-compartment; CL=clearance; OFV=Objective Function Value; Run=Model Number;

V=volume.

\* Description includes number of compartments and covariance structure, with '+' indicating correlated elements and',' separating independent elements.

The automated stepwise covariate search proceeded through nine forward steps, as shown in **Supplementary Table S2**. At each forward step, the covariate effect with the largest OFV drop was added if the drop was greater than 6.63. After the ninth forward step, no further covariates provided a large enough drop in OFV to be added to the model. A backward step was completed in which all covariates remain significant with no OFV increase greater than 10.3. No covariates were dropped in the backward step. The resultant model included covariate effects for: CLCR, weight (WT), and albumin (ALB) on CL; WT and ALB on V1; WT, ALB, and AGE on V2; and AGE on V3.

## **Supplementary Table S2: Model Building Trail for Stepwise Covariate Model Development**

<b>Step*</b>	<b>Added†</b>	<b>Starting OFV‡</b>	<b>New OFV§</b>	<b>ΔOFV  </b>	<b>P-value¶  </b>
1	CLCLR-5	15877.4	15704.0	-173.4	< 0.0001
2	V1WT-5	15704.0	15616.5	-87.5	< 0.0001
3	V2AGE-5	15616.5	15558.7	-57.8	< 0.0001
4	CLWT-5	15558.7	15515.2	-43.5	< 0.0001
5	CLALB-5	15515.2	15476.0	-39.2	< 0.0001
6	V2WT-5	15476.0	15444.9	-31.2	< 0.0001
7	V2ALB-5	15444.9	15424.6	-20.3	< 0.0001
8	V1ALB-5	15424.6	15403.8	-20.8	< 0.0001
9	V3AGE-5	15403.8	15392.0	-11.8	0.0006

CLALB=clearance on albumin-5; CLCLR-5=clearance on creatinine clearance, CLWT-5= clearance on weight, OFV= Objective Function Value; V1ALB-5= volume 1 on albumin; V1WT-5, volume 1 on weight, V2AGE=volume 2 on age, V2ALB-5=volume 2 on albumin; V2WT-5=volume 2 on weight; V3AGE-5=volume 3 on age.

\*Step= Stepwise Covariant Model step

†The covariate was added to the parameter after the step

‡Starting OFV before the step

§The OFV of accepted model

||Change in OFV with the step

¶P-value of the likelihood ratio test for the step.

The resulting Stepwise Covariate Model (SCM) was rerun with the covariance step and output tables as Run1001, but was unstable. The SCM path resulting in Run 1001 indicated at various levels that WT and ALB could be important covariates on V3, so Run 1002 was constructed which includes those variables as well. Run 1002 was stable, but failed the covariance step. The AGE effect on V3 was the last to be added in the SCM and was very close to being eliminated in the backward step. Removal of the AGE on V3 effect was tested in Run 1003 and the model was statistically significantly better. A diagonal omega was tested in Run 1004 to evaluate the correlation of random effects. The correlation structure suggested a correlation between CL and V2, and also between V1 and V3. This covariance structure was tested in Run 1005. A full block omega was tested in Run 1006, but was over-parameterized. Run 1007 and Run 1008 tested removal of AGE on V2 on the original (Run 1003) and new (Run 1005) random effects structures. In neither case could AGE on V2 be neglected, as they resulted in 70 and 82 point increases in OFV, respectively. Run 1005 was taken as the final model based on goodness of fit, estimate precision, and robustness. The models examined in this refinement stage are summarized in **Supplementary Table S3**.

**Supplementary Table S3: Model Building Trail for Covariate Model Refinement**

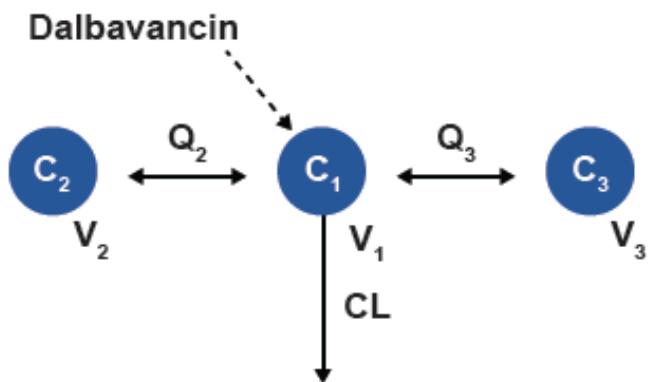
Run	Based on	OFV	$\Delta$ OFV	Description	Minimization Status	Covariance Step Status
1001	108	15392.0		CL(CLCR,WT,ALB) V1(WT,ALB) V2(WT, ALB AGE) V3(AGE), Omega(CL + V + V2, V3)	Failed	Failed
1002	1001	15386.5	-5.6	CL(CLCR,WT,ALB) V1(WT,ALB) V2(WT, ALB, AGE) V3(AGE,WT,ALB), Omega(CL + V + V2, V3)	Successful	Failed
1003	1002	15395.1	8.6	CL(CLCR,WT,ALB) V1(WT,ALB) V2(WT, ALB, AGE) V3(WT,ALB), Omega(CL + V + V2, V3)	Successful	Failed
1004	1003	15726.0	330.9	CL(CLCR,WT,ALB) V1(WT,ALB) V2(WT, ALB, AGE) V3(WT,ALB), Omega(CL, V, V2, V3)	Successful	Successful
1005	1004	15447.3	-278.8	CL(CLCR,WT,ALB) V1(WT,ALB) V2(WT, ALB, AGE) V3(WT,ALB), Omega(CL + V2, V1 + V3)	Successful	Successful
1006	1005	15344.4	-102.8	CL(CLCR,WT,ALB) V1(WT,ALB) V2(WT, ALB, AGE) V3(WT,ALB), Omega(CL + V1 + V2 + V3)	Successful	Failed
1008	1005	15517.1	69.9	CL(CLCR,WT,ALB) V1(WT,ALB) V2(WT, ALB) V3(WT,ALB), Omega(CL + V2, V1 + V3)	Successful	Successful

1007	1003	15477.0	81.9	CL(CL <sub>CR</sub> ,WT,ALB) V1(WT,ALB) V2(WT, ALB) V3(WT,ALB), Omega(CL + V + V <sub>2</sub> , V <sub>3</sub> )	Successful	Failed
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ALB=albumin; CL=clearance; CRCL=creatinine clearance, V=volume, WT=weight

**Supplementary Figure S1.** Diagram of the structural model.



CL=clearance; V=volume.

**Online Supplemental Table. Site numbers, Primary Investigators (PI), Study Sites and Institutional Review Board Names and Addresses for VER001-4, VER001-5, VER001-9 and DUR001-303**

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**VER001-5. Primary Investigator, Study Sites and IRB Names and Addresses**

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**VER001-9 Primary Investigator and Study Sites Names and Addresses**

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057	<a href="#">Kathleen Mullane, MD</a>	<p>Loyola University Medical Center 2160 S. First Avenue Maywood, IL 60153</p>
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065	<a href="#">David Solomon, MD</a>	<p>University of Arkansas for Medical Services 4301 West Markham, Slot 584 Little Rock, AR 72205</p>
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074	<a href="#">Coleman Rotstein, MD</a>	<p>Hamilton Health Sciences Henderson Site 711 Concession Street Hamilton, Ontario L8V1C3</p> <p>Hamilton Health Sciences General Site 237 Barton Street East Hamilton, Ontario L8L 2X2</p>
075	<a href="#">Charles, C. Bailey Jr., MD</a>	<p>Saddleback Memorial Medical Center 24451 Health Center Drive Laguna Hills, CA 92653</p> <p>Charles C. Bailey, Jr., M.D. Office 15 Mareblu, Ste 310 Aliso Viejo, CA 92656</p>

078	<a href="#">Kathleen Casey, MD</a>	Jersey Shore University Medical Center 1945 Route 33 Neptune, NJ 07754
081	<a href="#">James Tan, MD</a>	Summa Health System 525 East Market Street Akron, OH 44309  Summa Health System 75 Arch Street Suite 105 Akron, OH 44304
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**VER001-9 Primary Investigator and IRBs**

<b>Site #</b>	<b>Investigator Name</b>	<b>Name and Address of Institutional Review Board (IRB)</b>
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003	Arvind Gupta, MD	Sacred Heart Hospital IRB 421 Chew Street Allentown, PA 18102
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021	Robert Schwartz, MD	Lee Memorial Health System Institutional Review Committee 2776 Cleveland Avenue Fort Myers, FL 33901
022	Lawrence J. Eron, MD	Kaiser Hawaii IRB 501 Alakawa Street, Ste 201 Honolulu, HI 96817
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024	Norman Garrison, MD	Jackson Hospital IRB 1725 Pine Street Montgomery, AL 36106
025	Roger Schechter, MD	Palomar/Pomerado Hospital District Investigational Review Committee c/o Medical Staff Office Palomar Medical Center 555 E. Valley Parkway Escondido, CA 92025
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<b>Site #</b>	<b>Investigator Name</b>	<b>Name and Address of Institutional Review Board (IRB)</b>
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078	Kathleen Casey, MD	Jersey Shore University Medical Center IRB 1945 Route 33 Neptune, NJ 07754
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252	Mark Wilcox, MD	Leeds (West) Research Ethics Committee 6 <sup>th</sup> Floor, Welcome Wing The General Infirmary at Leeds Great Georges Street Leeds LS13EX UK
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<b>Novikovs, Nikolajs, MD</b> Sub-Investigator(s):  Oleinikovs, Vladimirs, MD Smolakova, Valentina	402	Daugavpils Regional Hospital Surgery department II Vasamicu Street 20 Daugavpils, Latvia LV-5417 37129403841
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Marina, Sonya, MD, Assoc. Prof.	Central: Ethics Committee for Multicenter Trials, 5 Sveta Nedelya Square, 1000 Sofia, Bulgaria  Chairperson: Aleksandar Oskar, MD  Local: Local Ethics Committee at UMHAT 'Aleksandrovska,' 'University Multiprofile Hospital for Active Treatment 'Aleksandrovska' EAD, Sofia, 1 Sveti Georgi Sofiiski Street, 1431 Sofia, Bulgaria  Chairperson: Zdravko Kamenov, Prof.

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**Hungary**

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