

Supplementary material

**Table S1.** Predicted and observed dose of monoclonal antibodies.

Age	BW (kg)	Observed Dose (mg)		Predicted	Ratio	Ratio
		PI based	CL based	Salisbury	Salisbury	CL based
Basiliximab, Adult Dose = 20 mg, Pediatric Dose = 12 mg/m², Liver transplantation, Ref [1]						
<2 years	10 (0.29 m²)	3.5	6.9	4.0	1.15	0.58
3.5 years	20 (0.79 m²)	9.5	8.7	8.0	0.84	0.92
8.6 years	35 (1.2 m²)	14.4	10.2	13.0	0.90	1.28
13.5 years	50 (1.4 m²)	16.8	17.8	16.0	0.95	0.90
Basiliximab, Adult Dose = 20 mg, Pediatric Dose = 12 mg/m², Renal transplantation, Ref [2]						
1-4 years	25 (0.92 m²)	11.0	8.1	10.0	0.91	1.23
6-12 years	40 (1.3 m²)	15.6	10.3	16.0	1.03	1.36
14-16 years	55 (1.6 m²)	19.2	16.2	17.0	0.89	1.05
Bevacizumab, Adult Dose = 10 mg/kg, Pediatric Dose = 10 mg/kg, CNS malignancies, Ref [3,4])						
11 months	8	80	158	112	1.40	0.71
31 months	16	160	266	224	1.40	0.84
25 months	11	110	201	154	1.40	0.77
Infliximab, Adult Dose = 5 mg/kg, Pediatric Dose = 5 mg/kg, Crohn's disease and ulcerative colitis, Ref [5-7]						
>6 years	40	200	280	245	1.23	0.88
6-17 years	45	225	318	263	1.17	0.83
0.7-3.1 years	15	75	54	105	1.40	1.94
0.2-6.25 years	25	125	121	175	1.40	1.45
Canakinumab, Adult Dose = 150 mg, Pediatric Dose = 2 mg/kg, if wt >40 kg then fixed dose of 150 mg SJIA, Ref [8-10]						
0.7-1.7 years	10	20	29	30	1.50	1.03
2.7-4.9 years	25	50	76	75	1.50	0.98
5.9-11.1 years	45	150	119	113	0.75	0.94
12-17.2 years	60	150	138	135	0.90	0.98
Canakinumab, Adult Dose = 150 mg, Pediatric Dose = 2 mg/kg, if wt >40 kg then fixed dose of 150 mg CAPS, Ref [8-10]						
<2 years	18	36	51	54	1.50	1.07
3.5 years	24	48	103	72	1.50	0.70
8.6 years	35	150	141	98	0.65	0.69
13.5 years	50	150	150	120	0.80	0.80
Daclizumab, Adult Dose = 1 mg/kg, Pediatric Dose = 1 mg/kg, acute organ rejection renal transplant, Ref [11,12]						
<5 years	12	12	28	17	1.40	0.60
6-12 years	29	29	58	41	1.40	0.70
13-17 years	52	52	78	57	1.10	0.74
Rilonacept, Adult Dose = 320 mg, Pediatric Dose = 4.4 mg/kg, sJIA, Ref [13])						
<6 years	20	88	98	128	1.45	1.30
6-11 years	40	176	222	224	1.27	1.01
12-17 years	50	220	320	256	1.16	0.80
Cetuximab, Adult Dose = 250 mg/m², Pediatric Dose = 250 mg/m², refractory Solid Tumors, Ref [14,15]						
1-12 years	30	300	169	259	0.86	1.53
13-18 years	55	400	301	367	0.92	1.22
Natalizumab, Adult Dose = 300 mg, Pediatric Dose = 3 mg/kg, Crohn's disease, Ref [16,17]						
11-17 years	50	150	239	240	1.60	1.01
Atezolizumab, Adult Dose = 1200 mg, Pediatric Dose = 15 mg/kg, metastatic solid tumors or hematologic malignancies, Ref [18]						
<2 years	9	137	158	158	1.38	1.60
2-<12 years	23	338	392	392	1.38	1.60
12-<18 years	52	773	896	896	0.82	0.95
Palivizumab, Adult Dose = 15 mg/kg, Pediatric Dose = 15 mg/kg, respiratory syncytial virus (RSV) , Ref [19,20]						
12.3 months (IM)	4.5	68	58	95	1.39	1.63
Tocilizumab, Adult Dose = 280 mg, Pediatric Dose = <30 kg = 10 mg/kg, >30 kg = 8 mg/kg, PJIA, Ref [21]						
5.2 years	20	200	119	112	0.56	0.94
13.1 years	50	400	158	224	0.56	1.21
Mepolizumab, Adult Dose = 100 mg, Pediatric Dose = <40 kg = 40 mg, ≥40 kg = 100 mg, severe eosinophilic asthma, Ref [22]						
8 years	27	40	45	54	1.35	1.20
10 years	50	100	75	80	0.80	1.33
Urttoxazumab, Adult Dose = 1 mg/kg, Pediatric Dose = 1 mg/kg, hemolytic-uremic syndrome, Ref [23]						
2.9 years	15	15	21	21	1.40	1.00
Abatacept, Adult Dose = 750 mg, Pediatric Dose = 10 mg/kg, JIA, Ref [24]						
6-17 years	50	500	731	600	1.20	0.82
Belatacept, Adult Dose = 5mg/kg, Pediatric Dose = 7.5 mg/kg, kidney transplant, Ref [25,26]						
13-17 years	59	442	277	312	0.70	1.12

**Eculizumab, Adult Dose = 900 mg, Pediatric Dose = 5-<10 kg = 300, 10-<20 kg, 20<30, 30-<40 kg = 600 mg, >40 kg = 900 mg, hemolytic-uremic syndrome, ref [5]**

Not known	8	300	NA	144	0.48	NA
	15	600	NA	270	0.45	NA
	25	600	NA	450	0.75	NA
	35	600	NA	585	0.98	NA
	50	900	NA	720	0.80	NA

**Adalimumab, Adult Dose = 40 mg, Pediatric Dose = 10-<15 kg = 10 mg, 15-<30 kg = 20 mg, 30-40 kg = 40 mg, JIA or Pediatric Uveitis, Ref [27]**

Not known	12	10	NA	10	0.96	NA
	25	20	NA	20	1.00	NA
	40	40	NA	28	0.70	NA

**Ustekinumab, Adult Dose = 45 mg, Pediatric Dose = 0.75 mg/kg for <60 kg, moderate to severe plaque psoriasis, Ref [28]**

12-17 years	40	30	NA	32	1.05	NA
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**Raxibacumab, Adult Dose = 40 mg/kg, Pediatric Dose = 80/kg (<10 kg), 60 mg/kg (>10-40 kg), 40 mg/kg (>40 mg/kg), Inhalational anthrax, Ref [29]**

Not known	10	800	NA	560	0.70	NA
	25	1500	NA	1400	0.93	NA
	50	2000	NA	2240	1.12	NA

**Obiltoximab, Adult Dose = 16 mg/kg, Pediatric Dose = <15 kg = 32 mg/kg, >15-40 kg = 24 mg/kg, >40 kg = 16 mg/kg, Inhalational anthrax, Ref [30]**

Not known	15	480	NA	336	0.70	NA
	25	600	NA	560	0.93	NA

Table S2: Predicted and observed dose of polyclonal antibodies.

Age	BW (kg)	Observed Dose (mg)		Predicted	Ratio	Ratio
		PI based	CL based	Salisbury	Salisbury	CL based
GAMMAPLEX 10% (IV), Adult Dose = 300-800 mg/kg, Pediatric Dose = 300 mg/kg, Ref [31]						
2-5 years	15	4500	NA	6300	1.40	NA
6-11 years	20	6000	NA	8400	1.40	NA
12-15 years	50	15000	NA	16800	1.12	NA
Gamunex-C (IV), Adult Dose = 300-600 mg/kg, Pediatric Dose = 300 mg/kg, Ref [32]						
2-5 years	15	4500	NA	6300	1.40	NA
6-11 years	20	6000	NA	8400	1.40	NA
12-15 years	50	15000	NA	16800	1.12	NA
Cuvitru (SC), Adult Dose = 220 mg/kg/week, Pediatric Dose = 220 mg/kg/week, Ref [33]						
2-<5 years	15	3300	NA	4620	1.40	NA
5-<12 years	20	4400	NA	6160	1.40	NA
12-16 years	50	11000	NA	12320	1.12	NA
Panzyga (IV), Adult Dose = 300-600 mg/kg, Pediatric Dose = 300 mg/kg, Ref [34]						
2-<6 years	20	6000	NA	8400	1.40	NA
6-<12 years	25	7500	NA	10500	1.40	NA
12-<16 years	50	15000	NA	16800	1.12	NA
Hizentra (SC), Adult Dose = 117 mg/kg, Pediatric Dose = 6-<12 years = 120 mg/kg, 12-<16 years = 115 mg/kg, Ref [35]						
6-<12 years	25	3000	NA	4095	1.37	NA
12-<16 years	50	5750	NA	6552	1.14	NA

**Table S3: Predicted and observed dose of polyclonal antibodies in premature and term neonates.**

<b>BW (kg)</b>	<b>Pediatric Observed Dose (mg/kg)</b>	<b>Pediatric Observed Dose (mg)</b>	<b>Pediatric Predicted Dose (mg)</b>	<b>Ratio</b>
<b>Gammagard (IV), Adult dose = 400-600 mg/kg [36]</b>				
1.1	500	550	616	1.12
1.1	750	825	616	1.12
<b>Sandoglobulin (IV), Adult dose = 400-600 mg/kg [37]</b>				
2.6	500	1300	1456	1.12
<b>Gamimune (IV), term, Adult dose = 400 mg/kg (Assumed)* [38]</b>				
2.87	250	718	1607	2.24
3.04	500	1520	1702	1.12
2.51	1000	2510	1406	0.56
<b>Venoglobulin (IV), Adult dose = 400 mg/kg (Assumed)* [36]</b>				
1.12	1000	1120	627	0.56
1.06	750	795	594	0.75
1.16	500	580	650	1.12

\*Adult dose was not known for these two polyclonal antibodies therefore, current dosing practice of an initial adult dose of 400 mg was chosen.

**Table S4: Predicted and observed dose of therapeutic protein (non-antibodies).**

Age	BW (kg)	Observed Dose (mg)		Predicted	Ratio	Ratio
		PI based	CL based	Salisbury	Salisbury	CL based
Bivalirudin, Adult Dose = 0.75 mg/kg, Pediatric Dose = 0.75/mg/kg, percutaneous coronary intervention, Ref [39–41]						
<30 days	4	3	8	4	1.41	0.47
31 days <2	8	6	17	9	1.41	0.52
2-<6	18	13	28	19	1.41	0.69
6-<16	41	31	50	38	1.23	0.76
Darbepoetin alfa, Adult Dose = 0.5 mcg/kg, Pediatric Dose = 0.5 mcg/kg, chronic kidney disease Ref [42]						
1-17 y	35	18	25	23	1.26	0.91
Darbepoetin alfa, Japanese, Adult Dose = 0.41 mcg/kg, Pediatric Dose = 0.43 & 0.37 mcg/kg, chronic kidney disease Ref [43]						
<12 y	25	11	16	14	1.30	0.87
>12 y	40	15	15	20	1.34	1.34
Erythropoietin, Adult = 50 U/kg, Pediatric Dose = 50 U/kg, end stage renal failure, Ref [44,45]						
9-12 y	27	1350	2625	1890	1.40	0.72
>12-16 y	41	2050	3500	2485	1.21	0.71
Interleukin 11, Adult = 50 mcg/kg, Pediatric Dose = 50 mcg/kg, solid tumors or lymphoma, [46]						
>1-3 y	9	433	665	607	1.40	0.91
>3-<13	26	1319	1776	1847	1.40	1.04
>13-<17	51	2532	3204	2822	1.11	0.88
Drotrecogin alfa (activated), Adult Dose = 24 mcg/kg, Pediatric Dose = 24 mcg/kg, chronic kidney disease, Ref [47,48]						
<1 year	6	144	150	202	1.40	1.34
1-8 y	25	600	531	840	1.40	1.58
>8-18 y	50	1200	796	1344	1.12	1.69
Glulisine, SC, Adult Dose = 0.15 U/kg, Pediatric Dose = 5.9 IU for children, 9.7 IU for adolescents, type 1 diabetes, [49]						
5-11 years	40	6	9	7	1.17	0.78
11-17 years	64	10	11	10	1.0	0.91
Regular Human Insulin (RHI) (SC), Adult Dose = 0.15 U/kg, Pediatric Dose = 5.9 IU for children, 9.7 IU for adolescents, type 1 diabetes, Ref [49,50]						
5-11 years	40	6	9	7	1.17	0.78
11-17 years	64	10	11	10	1.0	0.91
Growth Hormone (LB03002), Adult Dose = 4.7 mg, Pediatric Dose = 0.2 mg/kg, GH deficiency, Ref [51,52]						
7 years	25	5	2	2	0.47	1.0
Enfuvirtide (SC), Adult Dose = 90 mg, Pediatric Dose = 2 mg/kg, HIV-1 Infection, Ref [53,54]						
>5-<12	27	54	45	49	0.90	1.07
>12-<17 y	46	92	67	68	0.74	1.03
Peginterferon alpha 2a, Adult Dose = 180 mcg, Pediatric Dose = 104 mcg/m², Chronic hepatitis C, Ref [55]						
2-8 years	20 (0.8 m²)	83	NA	72	0.87	NA

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