

UMIN臨床試験登録システムへの登録状況

2012年度: 4/1~12/18

		2008年度	2009年度	2010年度	2011年度	2012年度
臨床研究数 (比率)		719	1537	1923	2274	1984
疾患区分1/Classification by specialty	内科学一般/Medicine in general	85 (11.8%)	131 (8.5%)	168 (8.7%)	222 (9.8%)	197 (9.9%)
	消化器内科学(消化管)/Gastroenterology	77 (10.7%)	183 (11.9%)	230 (12.0%)	275 (12.1%)	281 (14.2%)
	消化器内科学(肝・胆・膵)/Hepato-biliary-pancreatic medicine	77 (10.7%)	115 (7.5%)	169 (8.8%)	188 (8.3%)	165 (8.3%)
	循環器内科学/Cardiology	94 (13.1%)	192 (12.5%)	203 (10.6%)	209 (9.2%)	187 (9.4%)
	呼吸器内科学/Pneumology	87 (12.1%)	182 (11.8%)	223 (11.6%)	241 (10.6%)	166 (8.4%)
	内分泌・代謝病内科学/Endocrinology and Metabolism	79 (11.0%)	129 (8.4%)	176 (9.2%)	193 (8.5%)	175 (8.8%)
	血液・腫瘍内科学/Hematology and clinical oncology	108 (15.0%)	172 (11.2%)	203 (10.6%)	235 (10.3%)	204 (10.3%)
	腎臓内科学/Nephrology	57 (7.9%)	90 (5.9%)	79 (4.1%)	118 (5.2%)	108 (5.4%)
	神経内科学/Neurology	29 (4.0%)	48 (3.1%)	56 (2.9%)	97 (4.3%)	75 (3.8%)
	膠原病・アレルギー内科学/Clinical immunology	22 (3.1%)	52 (3.4%)	48 (2.5%)	68 (3.0%)	53 (2.7%)
	心療内科学/Psychosomatic Internal Medicine	5 (0.7%)	12 (0.8%)	1 (0.1%)	7 (0.3%)	7 (0.4%)
	感染症内科学/Infectious disease	17 (2.4%)	36 (2.3%)	53 (2.8%)	49 (2.2%)	28 (1.4%)
	老年内科学/Geriatrics	13 (1.8%)	26 (1.7%)	26 (1.4%)	49 (2.2%)	32 (1.6%)
	外科学一般/Surgery in general	20 (2.8%)	47 (3.1%)	45 (2.3%)	86 (3.8%)	59 (3.0%)
	消化器外科(消化管)/Gastrointestinal surgery	56 (7.8%)	154 (10.0%)	194 (10.1%)	228 (10.0%)	170 (8.6%)
	消化器外科(肝・胆・膵)/Hepato-biliary-pancreatic surgery	49 (6.8%)	74 (4.8%)	116 (6.0%)	130 (5.7%)	100 (5.0%)
	血管外科学/Vascular surgery	7 (1.0%)	22 (1.4%)	28 (1.5%)	28 (1.2%)	25 (1.3%)
	呼吸器外科学/Chest surgery	25 (3.5%)	55 (3.6%)	51 (2.7%)	79 (3.5%)	51 (2.6%)
	内分泌外科学/Endocrine surgery	8 (1.1%)	11 (0.7%)	7 (0.4%)	19 (0.8%)	15 (0.8%)
	乳腺外科学/Breast surgery	29 (4.0%)	45 (2.9%)	63 (3.3%)	94 (4.1%)	73 (3.7%)
	産婦人科学/Obstetrics and gynecology	19 (2.6%)	46 (3.0%)	57 (3.0%)	82 (3.6%)	70 (3.5%)
	小児科学/Pediatrics	21 (2.9%)	43 (2.8%)	66 (3.4%)	72 (3.2%)	62 (3.1%)
	眼科学/Ophthalmology	21 (2.9%)	49 (3.2%)	54 (2.8%)	111 (4.9%)	93 (4.7%)
	皮膚科学/Dermatology	14 (1.9%)	32 (2.1%)	41 (2.1%)	55 (2.4%)	49 (2.5%)
	精神神経科学/Psychiatry	34 (4.7%)	44 (2.9%)	61 (3.2%)	93 (4.1%)	72 (3.6%)
	耳鼻咽喉科学/Oto-rhino-laryngology	21 (2.9%)	51 (3.3%)	43 (2.2%)	75 (3.3%)	72 (3.6%)
	整形外科/Orthopedics	26 (3.6%)	63 (4.1%)	58 (3.0%)	86 (3.8%)	81 (4.1%)
	泌尿器科学/Urology	21 (2.9%)	81 (5.3%)	94 (4.9%)	79 (3.5%)	78 (3.9%)
	放射線医学/Radiology	38 (5.3%)	65 (4.2%)	102 (5.3%)	88 (3.9%)	84 (4.2%)
	麻酔科学/Anesthesiology	7 (1.0%)	21 (1.4%)	35 (1.8%)	65 (2.9%)	87 (4.4%)
	口腔外科学/Oral surgery	4 (0.6%)	19 (1.2%)	9 (0.5%)	22 (1.0%)	17 (0.9%)
	脳神経外科学/Neurosurgery	14 (1.9%)	46 (3.0%)	43 (2.2%)	73 (3.2%)	55 (2.8%)
	心臓血管外科学/Cardiovascular surgery	29 (4.0%)	22 (1.4%)	22 (1.1%)	29 (1.3%)	25 (1.3%)
	形成外科学/Plastic surgery	5 (0.7%)	13 (0.8%)	18 (0.9%)	17 (0.7%)	13 (0.7%)
	美容外科学/Aesthetic surgery	0 (0.0%)	3 (0.2%)	1 (0.1%)	3 (0.1%)	1 (0.1%)
	検査医学/Laboratory medicine	4 (0.6%)	10 (0.7%)	5 (0.3%)	13 (0.6%)	15 (0.8%)
	手術医学/Operative medicine	1 (0.1%)	9 (0.6%)	8 (0.4%)	13 (0.6%)	23 (1.2%)
	救急医学/Emergency medicine	15 (2.1%)	25 (1.6%)	24 (1.2%)	24 (1.1%)	24 (1.2%)
	輸血医学/Blood transfusion	1 (0.1%)	2 (0.1%)	1 (0.1%)	5 (0.2%)	4 (0.2%)
	集中治療医学/Intensive care medicine	8 (1.1%)	23 (1.5%)	32 (1.7%)	26 (1.1%)	17 (0.9%)
	リハビリテーション医学/Rehabilitation medicine	8 (1.1%)	31 (2.0%)	30 (1.6%)	52 (2.3%)	41 (2.1%)
歯学/Dental medicine	3 (0.4%)	29 (1.9%)	22 (1.1%)	44 (1.9%)	37 (1.9%)	
看護学/Nursing	6 (0.8%)	6 (0.4%)	14 (0.7%)	15 (0.7%)	17 (0.9%)	
該当せず/Not applicable	7 (1.0%)	32 (2.1%)	41 (2.1%)	37 (1.6%)	22 (1.1%)	
成人/Adult	0 (0.0%)	0 (0.0%)	59 (3.1%)	172 (7.6%)	161 (8.1%)	
小児/Child	0 (0.0%)	0 (0.0%)	9 (0.5%)	26 (1.1%)	18 (0.9%)	

目的2/Basic objectives2	安全性/Safety	46 (6.4%)	98 (6.4%)	125 (6.5%)	129 (5.7%)	134 (6.8%)
	有効性/Efficacy	251 (34.9%)	586 (38.1%)	639 (33.2%)	808 (35.5%)	703 (35.4%)
	安全性・有効性/Safety,Efficacy	331 (46.0%)	606 (39.4%)	851 (44.3%)	976 (42.9%)	818 (41.2%)
	生物学的・臨床的同等性/Bio-equivalence	9 (1.3%)	15 (1.0%)	21 (1.1%)	29 (1.3%)	28 (1.4%)
	生物学的利用性/Bio-availability	1 (0.1%)	18 (1.2%)	19 (1.0%)	28 (1.2%)	27 (1.4%)
	薬物動態/Pharmacokinetics	4 (0.6%)	37 (2.4%)	40 (2.1%)	30 (1.3%)	24 (1.2%)
	薬力学/Pharmacodynamics	6 (0.8%)	15 (1.0%)	14 (0.7%)	16 (0.7%)	13 (0.7%)
	薬物動態・薬力学/PK,PD	4 (0.6%)	10 (0.7%)	11 (0.6%)	19 (0.8%)	19 (1.0%)
	その他/Others	67 (9.3%)	152 (9.9%)	203 (10.6%)	239 (10.5%)	218 (11.0%)
	未選択	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
試験の性質1/Trial characteristics_1	検証的/Confirmatory	257 (35.7%)	480 (31.2%)	532 (27.7%)	598 (26.3%)	519 (26.2%)
	探索的/Exploratory	228 (31.7%)	414 (26.9%)	526 (27.4%)	605 (26.6%)	487 (24.5%)
	未選択	234 (32.5%)	643 (41.8%)	865 (45.0%)	1071 (47.1%)	978 (49.3%)
試験の性質2/Trial characteristics_2	説明的/Explanatory	95 (13.2%)	136 (8.8%)	188 (9.8%)	208 (9.1%)	176 (8.9%)
	実務的/Pragmatic	293 (40.8%)	574 (37.3%)	661 (34.4%)	778 (34.2%)	628 (31.7%)
	未選択	331 (46.0%)	827 (53.8%)	1074 (55.9%)	1288 (56.6%)	1180 (59.5%)
試験のフェーズ/Developmental phase	第I相/Phase I	28 (3.9%)	46 (3.0%)	75 (3.9%)	60 (2.6%)	58 (2.9%)
	第I・II相/Phase I,II	42 (5.8%)	45 (2.9%)	76 (4.0%)	62 (2.7%)	50 (2.5%)
	第II相/Phase II	128 (17.8%)	242 (15.7%)	270 (14.0%)	328 (14.4%)	219 (11.0%)
	第II・III相/Phase II,III	9 (1.3%)	17 (1.1%)	20 (1.0%)	19 (0.8%)	16 (0.8%)
	第III相/Phase III	42 (5.8%)	58 (3.8%)	58 (3.0%)	82 (3.6%)	63 (3.2%)
	第IV相/Phase IV	49 (6.8%)	83 (5.4%)	69 (3.6%)	70 (3.1%)	47 (2.4%)
	該当せず/Not applicable	177 (24.6%)	404 (26.3%)	513 (26.7%)	620 (27.3%)	541 (27.3%)
	未選択	244 (33.9%)	642 (41.8%)	842 (43.8%)	1033 (45.4%)	990 (49.9%)
試験の種類/Study type	介入/Interventional	618 (86.0%)	1282 (83.4%)	1585 (82.4%)	1858 (81.7%)	1535 (77.4%)
	観察/Observational	101 (14.0%)	255 (16.6%)	338 (17.6%)	416 (18.3%)	449 (22.6%)
	未選択	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
基本デザイン/Basic design	並行群間比較/Parallel	329 (45.8%)	565 (36.8%)	668 (34.7%)	748 (32.9%)	694 (35.0%)
	クロスオーバー試験/Cross-over	29 (4.0%)	77 (5.0%)	94 (4.9%)	105 (4.6%)	90 (4.5%)
	要因デザイン/Factorial	6 (0.8%)	4 (0.3%)	8 (0.4%)	18 (0.8%)	18 (0.9%)
	単群/Single arm	253 (35.2%)	633 (41.2%)	809 (42.1%)	983 (43.2%)	729 (36.7%)
	継続・拡大投与/expanded access	1 (0.1%)	3 (0.2%)	6 (0.3%)	4 (0.2%)	4 (0.2%)
	未選択	101 (14.0%)	255 (16.6%)	338 (17.6%)	416 (18.3%)	449 (22.6%)
ランダム化/Randomization	ランダム化/Randomized	330 (45.9%)	567 (36.9%)	694 (36.1%)	779 (34.3%)	710 (35.8%)
	非ランダム化/Non-randomized	288 (40.1%)	715 (46.5%)	891 (46.3%)	1079 (47.4%)	825 (41.6%)
	未選択	101 (14.0%)	255 (16.6%)	338 (17.6%)	416 (18.3%)	449 (22.6%)
ブラインド化/Blinding	オープン/Open -no one is blinded	437 (60.8%)	994 (64.7%)	1249 (65.0%)	1458 (64.1%)	1156 (58.3%)
	オープンだが測定者がブラインド化されている/Open -but assessor(s) are blinded	83 (11.5%)	130 (8.5%)	143 (7.4%)	165 (7.3%)	127 (6.4%)
	試験参加者がブラインド化されている単盲検/Single blind - participants are blinded	25 (3.5%)	45 (2.9%)	61 (3.2%)	76 (3.3%)	99 (5.0%)
	介入実施者・測定者がブラインド化されている単盲検/Single blind - investigator(s) and assessor(s) are blinded	9 (1.3%)	18 (1.2%)	21 (1.1%)	28 (1.2%)	26 (1.3%)
	二重盲検/Double blind -all involved are blinded	64 (8.9%)	95 (6.2%)	111 (5.8%)	131 (5.8%)	127 (6.4%)
	未選択	101 (14.0%)	255 (16.6%)	338 (17.6%)	416 (18.3%)	449 (22.6%)
コントロール/Control	プラセボ・シヤム対照/Placebo	63 (8.8%)	107 (7.0%)	133 (6.9%)	153 (6.7%)	138 (7.0%)
	無治療対照/No treatment	60 (8.3%)	121 (7.9%)	146 (7.6%)	176 (7.7%)	151 (7.6%)
	実薬・標準治療対照/Active	216 (30.0%)	388 (25.2%)	453 (23.6%)	530 (23.3%)	455 (22.9%)
	用量対照/Dose comparison	17 (2.4%)	34 (2.2%)	50 (2.6%)	42 (1.8%)	46 (2.3%)
	ヒストリカル/Historical	51 (7.1%)	136 (8.8%)	140 (7.3%)	147 (6.5%)	128 (6.5%)
	無対照/Uncontrolled	211 (29.3%)	496 (32.3%)	663 (34.5%)	810 (35.6%)	617 (31.1%)
	未選択	101 (14.0%)	255 (16.6%)	338 (17.6%)	416 (18.3%)	449 (22.6%)
試験結果の公開状況/Publication of results	未公表/Unpublished	581 (80.8%)	1343 (87.4%)	1776 (92.4%)	2137 (94.0%)	1909 (96.2%)
	中間解析等の途中公開/partially published	74 (10.3%)	106 (6.9%)	90 (4.7%)	91 (4.0%)	58 (2.9%)
	最終結果が公表されている/Published	64 (8.9%)	88 (5.7%)	57 (3.0%)	46 (2.0%)	17 (0.9%)
	未選択	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)