

Performance in Initiating and Delivering Clinical Research

University Hospitals of Leicester NHS Trust

Research & Innovation Directorate

Performance in Delivering Research

1st January 2015 to 31st December 2015

REC Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met ?
12/SC/0435	S38093 in addition to Donepezil in Alzheimer's patients	12	01/01/2015	Closed - In Follow Up	N
09/H0402/92	20080763 Panitumumab vs Cetuximab in Colorectal Cancer	10	05/01/2015	Closed - Follow Up Complete	Y
09/H0903/51	Phase 3 Study-Tivozanib in Patients with Advanced Renal Cell Carcinoma	5	05/01/2015	Closed - Follow Up Complete	N
10/H0806/106	Phase I Study of NY-ESO-1 +AS15 in Melanoma Version 1	4	05/01/2015	Closed - Follow Up Complete	N
12/NW/0082	Tiotropium + Olodaterol (Torracto [TM]) in COPD	5	24/01/2015	Closed - In Follow Up	Y
11/YH/0121	NCRN234 BOLT - LDE225 in patients with locally advanced or metastatic basal cell carcinoma	2	07/02/2015	Closed - In Follow Up	Y
13/LO/0578	BYM338 in COPD patients with cachexia	3	14/02/2015	Closed - In Follow Up	N
13/NW/0003	3-001:Study of ART-123 in Subjects with Severe Sepsis and Coagulopathy	6	24/02/2015	Closed - Follow Up Complete	N
11/WA/0309	BIAJ The IMAGINE 2 Study DRN594	6	01/03/2015	Closed - In Follow Up	N
13/EM/0097	A Safety Study Of Mepolizumab in Patients with Severe Asthma	8	13/03/2015	Closed - In Follow Up	N
11/LO/0608	NCRN322 TERRAIN: MDV3100 (ASP9785) vs. Bicalutamide Metastatic Prostate Cancer	12	20/03/2015	Closed - In Follow Up	N
12/EM/0206	STARLYTE: ARD10248 in patients with diffuse large B cell lymphoma	2	29/03/2015	Closed - Follow Up Complete	Y
12/LO/1125	Occlutech percutaneous PFO closure:Safety and Efficacy OPPOSE Registry	15	31/03/2015	Closed - In Follow Up	N
13/LO/0105	Saizen? in growth hormone deficiency (GHD) of adult onset	4	31/03/2015	Closed - Follow Up Complete	N
13/LO/0704	A study of allergen extracts in house dust mite associated asthma	3	31/03/2015	Closed - In Follow Up	N

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12/NE/0333	Tasquinimod in patients with advanced/ metastatic HCC,GC,OAC and RCC	10	22/04/2015	Closed - Follow Up Complete	N
12/LO/0928	MASERATI 100 Permacol Collagen Paste Study	10	30/04/2015	Open	Y
12/NE/0009	Study of GDC-0941 for the treatment of non-small cell lung cancer (FIGARO)	9	28/05/2015	Closed - Follow Up Complete	N
13/YH/0140	EDIFY: Ivabradine in heart failure with preserved ejection fraction	6	30/05/2015	Closed - Follow Up Complete	N
14/EM/1071	D5136C00007 Ticagrelor for sickle cell disease in paediatric patients	1	01/06/2015	Suspended	N/A
13/EM/0325	Oral Semaglutide Dose Range in Type 2 (SNAC)	8	08/06/2015	Closed - In Follow Up	N
12/SC/0434	DPMCF204 mannitol in CF aged 6-17 years	4	11/06/2015	Closed - In Follow Up	N
12/SC/0035	Austri: 6-month Safety and Benefit Study of SERETIDE in Children 4-11 years	6	19/06/2015	Closed - In Follow Up	Y
12/WS/0230	The NEFIGAN Trial	4	25/06/2015	Closed - In Follow Up	Y
14/EM/0101	1237.16 Tiotropium + Olodaterol (PHYSACTO[TM]) in COPD	3	15/02/2017	Open	N/A
13/EE/0326	Revacept/CS/02	4	30/06/2015	Closed - Follow Up Complete	N
14/EM/0186	A Phase 3 Study of Pacritinib in Patients with Myelofibrosis	2	30/06/2015	Open	Y
12/SC/0173	Saxagliptin with metformin in paediatric type 2 diabetes patients	2	02/07/2015	Closed - Follow Up Complete	N
13/LO/0219	GS-6624 in Subjects with Idiopathic Pulmonary Fibrosis (RAINIER)	2	02/07/2015	Closed - Follow Up Complete	N
12/NW/0242	Clinical trial of an investigational medicinal product (CTIMP)	15	07/07/2015	Closed - Follow Up Complete	N
13/LO/1911	Comparison of Lantus, Lixisenatide and Lixilan in Type 2 diabetes	3	10/07/2015	Closed - In Follow Up	N
11/SC/0499	A UK Phase IIIB expanded access study of INC424 in myelofibrosis	3	13/07/2015	Closed - Follow Up Complete	Y
12/EM/0204	Safety and tolerability of ONO-4059 in patients with NHL & CLL	7	15/07/2015	Open	Y
13/NE/0001	NN7088-3885 Paediatric PTP Study in Haemophilia A	1	30/07/2015	Closed - In Follow Up	Y

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12/EM/0308	SCULPTURE Extension Study	2	01/08/2015	Closed - In Follow Up	Y
10/H0406/41	ABSORB Extend	15	13/08/2015	Closed - In Follow Up	N
13/EM/0149	15961 GadaCAD1	15	31/08/2015	Closed - In Follow Up	Y
13/EM/0414	Study of Eosinophilic Granulomatosis with Polyangiitis and Mepolizumab	4	03/09/2015	Closed - In Follow Up	Y
14/EM/1059	047 FIT (Fostamatinib for Immune Thrombocytopenia) Study	3	31/03/2016	Open	N/A
14/SC/0185	AWARD-9 (GBDI Study)	5	22/09/2015	Closed - In Follow Up	N
13/LO/0326	9090-14: A Study of Ganetespib in advanced lung cancer	6	30/09/2015	Closed - In Follow Up	Y
14/EM/0209	Colourstart? Test 73 mcg Cutaneous Patch. TDL-CS-001 Version 1.0	50	30/09/2015	Closed - Follow Up Complete	N
13/SC/0384	Tremilimumba in pleural or peritoneal malignant mesothelioma	2	01/10/2015	Closed - In Follow Up	Y
14/NW/0017	TERI-PRO	6	01/10/2015	Closed - In Follow Up	N/A
14/EE/0102	ENSURE in AF (atrial fibrillation) study	9	02/10/2015	Closed - In Follow Up	N
13/EM/0230	VS-6063 Phase II Mesothelioma study	10	06/10/2015	Closed - In Follow Up	Y
14/NE/1072	GB29260 - Lebrikizumab in patients with uncontrolled asthma.	4	07/02/2017	Open	N/A
12/EM/0349	AUY922 in NSCLC patients with EGFR mutations after TKI treatment	3	16/10/2015	Closed - In Follow Up	Y
09/H0406/110	LCZ696 vs enalapril in chronic heart failure	6	31/10/2015	Closed - In Follow Up	Y
13/LO/1766	EMR 100070-001: Phase I study of MSB0010718C in solid tumors	3	31/10/2015	Suspended	N/A
12/LO/0803	AZD5363 in patients with advanced or metastatic breast cancer (BEECH)	10	31/10/2016	Open	N/A
13/EE/0377	Elagolix in the treatment of menstrual bleeding with Uterine Fibroids	4	30/11/2015	Closed - In Follow Up	N
14/WS/0103	A Study of LEE011 in combination with Fulvestrant and BYL719 or BKM120	15	11/09/2019	Open	N/A
12/YH/0475	GP28331 - A PHASE Ib study - CHRONIC LYMPHOCYTIC LEUKAEMIA	5	15/12/2015	Open	Y
12/LO/0806	Aflibercept SQoP (AFLIBC06097)	5	31/12/2015	Closed - Follow Up Complete	Y

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13/EM/0084	Baxter 261201:PEGylated Recombinant Factor VIII in Severe Hemophilia A	1	31/12/2015	Closed - In Follow Up	Y
14/NW/1405	Treatment of chronic cough with PA101	4	31/12/2015	Closed - In Follow Up	Y
09/H0706/22	Aliskiren vs enalapril in chronic heart failure	5	01/01/2016	Closed - Follow Up Complete	N
08/H0502/133	BH21260- Mircera? vs. reference ESAs in CKD patients (SUB STUDY)	10	01/01/2016	Withdrawn	N
12/NE/0314	NN7999-3774, NNC0156-0009 in paediatric, previously treated subjects	1	01/01/2016	Closed - In Follow Up	Y
13/YH/0003	Ibrutinib in Chronic Lymphocytic Leukaemia/Small Lymphocytic Lymphoma	2	07/01/2016	Closed - In Follow Up	N
13/SC/0102	MK3475-010-00	3	20/01/2016	Closed - In Follow Up	Y
14/LO/0865	Phase 2 Study of Fostamatinib for Subjects with IgA Nephropathy	1	28/01/2016	Open	Y
13/EM/0423	GWP42004 in Type 2 diabetes	6	30/01/2016	Closed - In Follow Up	Y
12/EM/0395	EUCLID ? Examining use of ticagrelor in PAD patients	30	01/02/2016	Closed - In Follow Up	Y
14/NE/1214	A Phase 2 Veliparib plus Chemotherapy Study in Non-Squamous NSCLC	24	01/02/2016	Open	N/A
13/NE/0344	A monotherapy study of ertugliflozin in participants with T2DM	7	04/02/2016	Closed - In Follow Up	N
13/LO/1714	NOX-H94 in ESA-hyporesponsive anaemia in dialysis patients V2.0	2	15/02/2016	Open	N/A
13/LO/0491	CATCH-AMI	9	29/02/2016	Closed - In Follow Up	N
14/SW/1062	ACP-196 in subjects with Relapsed or Refractory de Novo ABC DLBCL	17	03/03/2016	Open	N/A
13/WA/0269	Elagolix in the Treatment of Endometriosis-Associated Pain (2)	6	18/03/2016	Closed - In Follow Up	Y
13/EE/0241	SIGNATURE Study CAIN457AGB01	2	31/03/2016	Closed - In Follow Up	Y
14/NW/0218	Finesse vs. Pen for Bolus Insulin in T2 DM, revision G	8	01/04/2016	Open	N/A
11/EM/0180	WA25204RA with CV Outcomes (Entracte Study)	6	22/04/2016	Closed - In Follow Up	N
10/MRA00/84	LDK378-Dose Escalation/Expansion study in patients with ALK+ tumour	2	31/05/2016	Closed - Follow Up Complete	Y

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14/EE/1001	OTO-104 in Meniere's Disease	10	31/05/2016	Closed - In Follow Up	Y
14/LO/1798	GO29294 Anti-PDL1 Bladder Cancer Phase III Version 1.0	5	01/06/2016	Open	N/A
15/SC/0054	CheckMate 238: CHECKpoint pathway and nivolumAb clinical Trial Evaluation 238	5	01/06/2016	Closed - Follow Up Complete	N
13/WM/0451	AMG 337 with MET Amplified Gastric, Esophageal or other solid tumours	3	08/06/2016	Closed - Follow Up Complete	N
15/LO/0718	MEPO PK-PD Paediatric Study in Severe Eosinophilic Asthma	2	30/06/2016	Open	N/A
14/EE/0076	ASSURE	6	13/07/2016	Closed - In Follow Up	Y
12/EM/0018	CANTOS- CACZ885M2301 Canakinumab in postMI patients with raised hsCRP	10	25/07/2016	Closed - In Follow Up	N
14/LO/1426	Biomarker Study with T-Vec in Unresected Stage IIIB to IVM1c Melanoma	5	08/08/2016	Open	N/A
13/EM/0251	Serelaxin when added to standard therapy in acute heart failure	6	28/08/2016	Open	Y
14/SC/0181	Elagolix in Endometriosis Associated Pain Extension Study	6	31/08/2016	Open	N/A
13/LO/0033	GO28509 PEGGY - Phase 2 study of GDC-0941 in metastatic breast cancer	2	01/09/2016	Closed - In Follow Up	Y
12/SC/0139	SafeHer: Safety study with subcutaneous Trastuzumab in breast cancer	10	23/09/2016	Open	N/A
11/LO/0954	1200.131 LUX-Head & Neck 2; Afatinib in Squamous Cell Carcinoma	5	28/09/2016	Open	N/A
13/SC/0092	CBAF312A2304 siponimod in secondary progressive multiple sclerosis v1	6	29/09/2016	Closed - In Follow Up	N
14/EM/0143	An Extension Study to MEA115661 in Severe Asthma	6	01/10/2016	Closed - In Follow Up	N
14/EM/0160	AEGIS-I, Phase II, dose ranging study of CSL112 in Acute MI	10	03/10/2016	Open	N/A
15/NE/0167	MLN9708 in Multiple Myeloma Not Treated with Stem Cell transplantation	4	03/10/2016	Open	N/A
12/LO/1825	Rilotumumab (AMG 102) with ECX in advanced gastric cancer	3	17/10/2016	Closed - In Follow Up	Y

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12/WM/0348	INCB 18424-357 The RELIEF study	10	30/10/2016	Closed - In Follow Up	N
14/EM/1068	Open label, phase 3 trial comparing Mylans Glargine with Lantus	5	30/10/2016	Closed - In Follow Up	N
13/SC/0616	COPD Exacerbation Vaccine Study - CCRN 2856 (COPD)	10	04/11/2016	Closed - In Follow Up	Y
15/WM/0009	Daratumumab + VMP vs VMP only in newly diagnosed multiple myeloma	3	15/11/2016	Open	N/A
15/NW/0028	A Phase 3 Study to Investigate the long term safety and efficacy of ZS	10	01/12/2016	Closed - In Follow Up	Y
14/LO/1996	VS-6063-104 Phase 1 study in relapsed malignant mesothelioma	14	14/12/2016	Open	N/A
13/ES/0005	Azacitidine in Subjects with IPSS Lower-risk Myelodysplastic Syndromes	6	25/12/2016	Open	N/A
14/SC/1311	Daptomycin in paediatric patients with AHO (infection of the bone)	1	30/12/2016	Open	N/A
12/LO/1697	A 2 year study to investigate belimumab in membranous nephropathy	3	31/12/2016	Open	N/A
13/ES/0088	The Effects of Serelaxin in Coronary Artery Disease	30	31/12/2016	Open	N/A
12/LO/1313	ROX CONTROL HTN STUDY: Protocol RH-02 Version 1.0, June 20, 2012	20	01/01/2017	Closed - Follow Up Complete	N
14/EM/1267	LCZ696 in patients from Paradigm HF study	7	27/01/2017	Open	N/A
15/NW/0507	1311.14 BI655066 v placebo in patients with uncontrolled severe asthma	2	27/02/2017	Open	N/A
14/SS/1048	156-13-210: Trial to Compare the Efficacy and Safety of Tolvaptan	5	31/03/2017	Open	Y
14/SC/0065	The CANVAS-R TRIAL - DRN2487	8	01/04/2017	Closed - In Follow Up	Y
15/EE/0161	Empagliflozin in patients with Type 1 Diabetes Mellitus (EASE-2).	5	04/04/2017	Open	N/A
12/LO/0491	Surgical Replacement & Transcatheter Aortic Valve Implantation SURTAVI	5	15/04/2017	Open	N/A
09/H0405/44	Neratinib after Trastuzumab in early stage breast cancer.	10	25/04/2017	Closed - In Follow Up	N

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13/EM/0284	LDK378 vs Chemo in ALK+ NSCLC in patients who failed crizotinib	10	13/07/2017	Closed - In Follow Up	N
13/LO/1517	Dolomites - CCRN 2158	2	15/07/2017	Open	Y
15/NW/0319	Efficacy and safety of LX4211 added to insulin in Type 1 Diabetes	6	31/07/2017	Open	N/A
14/WM/1055	Masitinib/Placebo + FOLFIRI in Metastatic Colorectal Cancer V1.0	5	01/09/2017	Open	N/A
11/EE/0311	MO25455	5	01/10/2017	Closed - In Follow Up	Y
14/EM/1060	049 FIT (Fostamatinib for Immune Thrombocytopenia) Extension Study	3	09/10/2017	Open	N/A
15/NW/0668	FUTURE 5	10	27/10/2017	Open	N/A
14/LO/1406	Open-label study of GDC-0199 in follicular lymphoma patients	5	30/10/2017	Open	N/A
15/EM/0247	Effect of Tralokinumab on airway inflammation in asthma	10	31/10/2017	Open	N/A
14/LO/2011	DUAL antithrombotic therapy with dabigatran etexilate (RE-DUAL PCI)	10	31/10/2017	Open	N/A
13/EM/0476	ABSORB UK Registry V1	30	17/11/2017	Open	N/A
09/H0402/101	The Effects of JNJ-28431754 on Cardiovascular Outcomes (CANVAS Study)	5	18/11/2017	Closed - In Follow Up	Y
11/AL/0327	B1871019 Phase 2 Study in Polycystic Kidney Disease	2	08/12/2017	Closed - In Follow Up	Y
14/NW/1248	Tralokinumab in severe asthma	4	22/12/2017	Open	N/A
14/NE/0105	Momelotinib vs. Ruxolitinib in subjects with Myelofibrosis	3	29/12/2017	Open	Y
10/H0808/109	EXCEL Clinical Trial 1.0 8th June 2010	25	31/12/2017	Closed - In Follow Up	Y
14/YH/0141	reMARQable v3.1	25	01/01/2018	Suspended	N/A
14/LO/0818	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC	10	22/01/2018	Closed - In Follow Up	N
11/EE/0291	Efficacy and Safety of Lenalidomide/Dexamethasone +/- Elotuzumab in MM	7	31/01/2018	Closed - In Follow Up	N
11/EM/0225	R-CHOP vs G-CHOP in previously untreated patients with DLBCL	5	01/02/2018	Closed - Follow Up Complete	N

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14/LO/1443	Pyrenees	5	01/02/2018	Open	N/A
13/LO/0418	SILDENAFIL IN NEONATES WITH PERSISTENT PULMONARY HYPERTENSION	3	01/03/2018	Open	N/A
12/WM/0341	AMG 145 and Statin Therapy in patients with Cardiovascular Disease	10	01/03/2018	Closed - In Follow Up	Y
13/NE/0125	PRESTO Neo.1.C/E	4	26/03/2018	Open	N/A
15/YH/0125	Phase 1b/2 Participants with Waldenström Macroglobulinemia ACE-WM-001	6	14/04/2018	Open	N/A
13/NI/0148	WB28182 The effect of lebrikizumab in patients with severe asthma	12	01/05/2018	Open	Y
11/LO/1408	ABSORB II RANDOMIZED CONTROLLED TRIAL	10	17/05/2018	Closed - In Follow Up	Y
13/NW/0692	CARMELINA DM CV outcome study 1218.22	10	31/05/2018	Open	Y
11/AL/0042	Exenatide Study of Cardiovascular Event Lowering (EXSCEL)	7	31/05/2018	Closed - Follow Up Complete	N
14/NE/1018	Benralizumab treatment in moderate to very severe COPD (GALATHEA)	6	01/06/2018	Open	Y
15/LO/0288	Moxetumomab Pasudotox in Relapsed/Refractory Hairy Cell Leukaemia	3	06/06/2018	Open	N/A
15/EM/0135	Phase 2 Study in Mantle Cell Lymphoma ACE-LY-004	4	15/06/2018	Open	N/A
15/WS/0135	GS-US-401-1757 A Phase 1b Dose Escalation and Dose Expansion Study	6	15/06/2018	Open	N/A
14/NW/0001	Continuation Study of Prophylactic BAX 855 in PTP with Haemophilia A	1	27/06/2018	Open	Y
15/LO/0519	AI438-047: Attachment inhibitor study in HTE patients with MDR HIV-1	2	06/08/2018	Open	N/A
13/LO/1328	PARAGON- LCZ696 vs valsartan in patients with chronic heart failure	10	15/08/2018	Open	N/A
13/SC/0490	Lebrikizumab in adolescent patients with uncontrolled asthma	5	31/08/2018	Open	Y
15/LO/0861	Safety and effectiveness of SAR156597 in the treatment of IPF	4	31/08/2018	Open	N/A
15/LO/0545	CARAT - RTSY03	10	30/09/2018	Open	Y
15/NW/0152	MetaPHer	5	01/11/2018	Open	N/A

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10/MREC00/61	An Open Label, Multicenter, randomized, phase III study to investigate the efficacy and safety	16	31/12/2018	Closed - In Follow Up	N
12/WM/0039	InovateHF	10	31/12/2018	Closed - In Follow Up	Y
14/LO/0673	MLN9708 in Multiple Myeloma after Autologous Stem Cell Transplant	8	31/01/2019	Open	N/A
13/NW/0006	Phase III study of Brentuximab vedotin in T-cell lymphoma patients	3	28/02/2019	Open	N/A
13/NW/0283	Global Leaders Study V1.0	100	01/03/2019	Closed - In Follow Up	N
12/LO/0460	EURO-CTO	5	02/03/2019	Closed - In Follow Up	N
14/ES/0001	Ertugliflozin in participants with T2DM & Vascular disease	7	30/04/2019	Closed - In Follow Up	N
11/SS/0054	RESPOND CRT	10	06/05/2019	Closed - In Follow Up	Y
14/EM/0034	GO28667 - PH III, OPEN-LABEL, IN RELAPSED/REFRACTORY PATIENTS WITH CLL	3	15/05/2019	Open	N/A
15/EM/0333	GS-US-401-1787, Open label Study - Long-term Safety of ONO/GS-4059	13	30/08/2019	Open	N/A
14/EM/1003	Study to evaluate safety & efficacy of Blisibimod in IgA Nephropathy	4	14/09/2019	Open	Y
13/WM/0114	SHINE MCL3002	3	10/10/2019	Closed - In Follow Up	N
13/EM/0340	ABT-199 Monotherapy in Relapsed/Refractory CLL With the 17p Deletion	5	31/10/2019	Closed - In Follow Up	N
12/LO/1950	C25003 Ph3 A+AVD vs ABVD Frontline in Patients with Hodgkin Lymphoma	24	27/11/2019	Open	N/A
08/H0502/132	BH21260- Mircera? vs. reference ESAs in CKD patients	20	31/12/2019	Closed - Follow Up Complete	N
15/EM/0077	Long-term Access Programme for Subjects who Participated in MEA115921	4	29/05/2020	Open	Y
14/WM/0170	Phase III study of Momelotinib in Patients with Myelofibrosis	3	01/10/2020	Open	N/A
14/YH/0086	RESPOND Protocol Number: TP6461	10	11/12/2020	Open	N/A
14/LO/1050	Bosutinib vs Imatinib in Newly Diagnosed CML	7	31/12/2020	Closed - In Follow Up	N

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15/LO/0691	Nivolumab monotherapy in patients with Non-Small Cell Lung Cancer	9	15/05/2021	Open	N/A
15/EM/0344	MORAb009-201 Amatuximab in Unresectable Malignant Pleural Mesothelioma	5	03/01/2022	Open	N/A
11/NW/0298	Phase III GA101 or rituximab plus chemo in 1st line indolent NHL	5	28/02/2022	Closed - In Follow Up	Y
09/WSE04/55	BO21004 - RO5072759 Safety and Efficacy Chemo Combo in untreated CLL	5	01/04/2022	Closed - Follow Up Complete	Y
13/LO/0021	PRESENT	10	14/12/2023	Open	N/A
13/EM/0460	Study of Adjuvant Kadcyla vs Herceptin, HER2+ve Primary Breast Cancer	6	23/01/2024	Closed - In Follow Up	N
12/EM/0284	A longterm Safety study for asthmatic subjects	6	21/04/2031	Closed - In Follow Up	N
13/EE/0345	FGF117360 Clinical study using drug GSK3052230 in Subjects with Cancer	5	30/10/2031	Open	N/A