

LATEST UK GENE THERAPY RESEARCH 1993-2003 (January 2004)

GTAC NO.	PROTOCOL NAME	DETAILS	CENTRE	OUTLINE APPROVAL	VECTOR	GENE	CELL LINE	NO. OF PATIENTS
01	Adenosine deaminase gene transfer in a child with severe combined immunodeficiency syndrome	SCID-ADA	Institute of Child Health/Great Ormond Street Hospital	1-93	Retrovirus	ADA	pOAM-P1	1 CLOSED
02	Gene Therapy Research for Cystic Fibrosis	CF Nasal trial	Royal Brompton Hospital	3-93	Plasmid	CFTR	<i>E. coli</i> DM5α	15 CLOSED
03	A pilot study of idiotypic vaccination for follicular B-cell lymphoma using a genetic approach	B-cell lymphoma	MRC Cambridge	7-93	Plasmid	anti-idiotypic immunoglobulin	<i>E. coli</i>	7 CLOSED
04	Use of gene transfer to determine the role of tumour cells in bone marrow used for autologous transplantation and the efficiency of immunomagnetic "purging" the bone marrow	Neuroblastoma	ICRF Bristol	2-94	Retrovirus	LNL-6/neo G1N-neo	PA317	Trial withdrawn
05	Gene Therapy for metastatic melanoma: Assessment of expression of DNA constructs directly injected into	Metastatic melanoma	ICRF Oxford	5-94	plasmid	IL-2	<i>E. coli</i> JM109	23 CLOSED

GTAC NO.	PROTOCOL NAME	DETAILS	CENTRE	OUTLINE APPROVAL	VECTOR	GENE	CELL LINE	NO. OF PATIENTS
	metastases							
06	The treatment of metastatic malignant melanoma with autologous melanoma cells that have been genetically engineered to secrete IL-2	Metastatic melanoma	Institute of Cancer Research; Royal Marsden Hospital	2-94	Retrovirus	IL-2	GP+env AM12	12 CLOSED
07	Towards gene therapy for cystic fibrosis	CF Nasal trial	Oxford; Cambridge	2-94	Plasmid	CFTR	<i>E. coli</i>	18 CLOSED
08	Gene Therapy Research for Cystic Fibrosis	CF Nasal trial	Edinburgh	5-94	Plasmid	CFTR	<i>E. coli</i>	16 CLOSED
09	Gene Therapy Research for Cystic Fibrosis	CF Lung trial	Royal Brompton Hospital	9-94	Plasmid	CFTR	<i>E. coli</i>	16 of 16 CLOSED
10	Transfer of the Human Multi-drug Resistance Gene into the Haemopoietic Cells of Patients Undergoing High Dose Therapy and Autologous Stem Cell Transplantation for Malignant Lymphoma	Lymphoma	University College London Medical School	12-94	Retrovirus	MDR-1	AMI2M1	3 CLOSED
11	Genetic prodrug activation therapy for breast cancer	Breast Cancer	Hammersmith Hospital	10-95	plasmid	Cytosine deaminase	<i>E. coli</i>	12 CLOSED
12	Use of a recombinant vaccinia virus for therapy of cervical cancer	Cervical Carcinoma	University of Wales, Cardiff	6-95	Vaccinia	TA-HPV	MRC5	1+8 CLOSED

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12A	Use of a recombinant Vaccinia vaccine (TA-HPV) to treat Cervical intraepithelial neoplasia III	Cervical intraepithelial neoplasia III	University of Wales, Cardiff	5-96	Vaccinia	HPV E6 and E7	MRC5	12 CLOSED
12B	Use of a recombinant Vaccinia vaccine (TA-HPV) to treat Cervical intraepithelial neoplasia III	Cervical intraepithelial neoplasia III	University of Wales, Cardiff; University of Manchester	8-97	Vaccinia	HPV E6 and E7	MRC5	8 CLOSED
12C	Use of recombinant Vaccinia vaccine (TA-HPV) to treat Vulval intraepithelial neoplasia III	Vulval Intraepithelial Neoplasia III	St Mary's Hospital, Manchester	1-00	Vaccinia	HPV E6 and E7	MRC5	18 CLOSED
12 D	Use of a recombinant Vaccinia vaccine (TA-HPV) to treat Ano-genital intraepithelial neoplasia III	Ano-genital intraepithelial neoplasia III	Addenbrooke's Hospital, Cambridge	4-00	Vaccinia	HPV E6 and E7	MRC5	12 CLOSED
13	A proposal to study the efficacy of transplantation of autologous retroviral transduced bone marrow in patients homozygous for the W402X mutation (Hurlers syndrome)	Hurlers Syndrome	Royal Manchester Children's Hospital, Manchester	12-95	Retrovirus	pLX	GP+env AM12	3 CLOSED
14	Phase I, Open-Label, Dose-Escalation Trial of Intra-Tumoral Injection with an E1B	Head and Neck Cancer	Beatson Oncology Centre, Glasgow	1-96	Adenovirus	E1B deleted	HEK293	22 CLOSED

GTAC NO.	PROTOCOL NAME	DETAILS	CENTRE	OUTLINE APPROVAL	VECTOR	GENE	CELL LINE	NO. OF PATIENTS
	Attenuated Adenovirus ONYX-015, into Recurrent and Locally Advanced p53(-) Squamous Cell Tumours of the Head and Neck							
14A	A phase II trial of intravenous cisplatin, 5-FU and intratumoral injection with ONYX-015 into recurrent, chemotherapy naive squamous cell tumours of the head and neck	Head and Neck Cancer Phase II Study	Beatson Oncology Centre, Glasgow	7-97	Adenovirus	E1B deleted	HEK293	37 CLOSED
14 B	Phase I, Open-Label, Dose-Escalation Trial of Intraperitoneal Injection with an E1B Attenuated Adenovirus in patients with recurrent/refractory ovarian carcinomas	Recurrent/ refractory ovarian cancer	Beatson Oncology Centre, Glasgow	2-97	Adenovirus	E1B deleted	HEK293	12 CLOSED
15	Towards gene therapy for Cystic Fibrosis	CF Nasal Trial	Oxford/Cambridge/Leeds/ Manchester Consortium	5-96	Plasmid	CFTR	<i>E. COLI</i>	11 CLOSED
16	Phase I study in patients with recurrent metastatic squamous cell carcinoma of the head and neck using SCH 58500 (rAd/p53)	Head and Neck Cancer	Institute of Cancer Research; Royal Marsden Hospital	9-96	Adenovirus	p53	HEK293	Trial never commenced in UK CLOSED
17	Gene therapy for	CF Lung and	Royal Brompton Hospital	11-96	Plasmid	CFTR # 67	<i>E. COLI</i>	16

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	Cystic Fibrosis Delivery to nasal epithelium and lung by nebulisation of the pCFICFTR/#67	Nasal Trial					TGI	CLOSED
18	A Phase I dose-escalation study of intratumoral injection with modified HSV Type I (ICP 34.5) into primary and recurrent malignant glioma	Glioblastoma	Beatson Oncology Centre, Glasgow	12-96	HSV	ICP34.5 deleted	BHK 21/C13	9 CLOSED
18A	A Phase I dose-escalation study of intratumoral injection with modified HSV Type I (ICP 34.5) into primary and recurrent malignant glioma	Glioblastoma	Beatson Oncology Centre, Glasgow; Institute of Neurological Sciences, Glasgow; Queen Elizabeth Hospital, Birmingham	7-99	HSV	ICP34.5 deleted	BHK 21/C13	12 CLOSED
18B	A study of the safety of the modified Herpes simplex virus (HSV 1716) when injected into tumour bearing brain following resection of recurrent or newly diagnosed high grade glioma	Glioblastoma	Beatson Oncology Centre, Glasgow.	11-00	HSV	ICP34.5 deleted	BHK 21/C13	8 CLOSED
19	GTI 0115 radiation and infection of murine cells producing HSV TK vector followed by intravenous	Glioblastoma	Beatson Oncology Centre, Glasgow; Institute of Neurological Sciences, Glasgow	3-97	Retrovirus	TK	PA317	Trial withdrawn

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	ganciclovir against the efficacy of surgery and radiation in the treatment of newly diagnosed previously untreated glioblastoma (tumour site).							
20	A clinical trial with Ad-5CMV-p53 vector in patients with ascites formation.	Gastrointestinal cancer, malignant cancer ascites	Royal Marsden Hospital, London	4-97	Adenovirus	P53	Hek293	1 CLOSED
21	Phase II study of immunotherapy of advanced breast cancer by repeated intramuscular injection of recombinant vaccinia viruses containing sequences coding for human MUC-1 and IL2 (TG1031).	Breast Cancer	Guy's Hospital, London	11-97	Vaccinia	MUC-1 IL2	-	14 CLOSED
22	A multiple ascending dose study evaluating the safety and the gene transduction into malignant cells after the administration of EIA-lipid complex by intra-peritoneal administration in patients with epithelial ovarian cancer who	Ovarian Cancer	The John Radcliffe Hospital, Oxford; Guy's and St Thomas's Cancer Centre, London; Royal Marsden Hospital, London; St George's Medical School, London.	9-97	Plasmid	E1A HER2/ neu	<i>E. coli</i> STBL2	22 CLOSED

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	over express HER-2/neu.							
23	A pilot study of recombinant CEA vaccinia virus vaccine with post vaccination CEA peptide challenge in combination with 5-fluorouracil and folinic acid in the treatment of colorectal cancer (Phase I subcutaneous).	Colorectal Cancer	Queen Elizabeth Hospital, Birmingham	3-98	Vaccinia	CEA	CV1	Trial not yet open
24	A phase I study of intraperitoneal administration of a replication deficient adenovirus carrying a nitroreductase gene in ovarian cancer patients.	Ovarian Cancer	City Hospital NHS Trust and University Hospital NHS Trust Birmingham	3-98	Adenovirus	Nitroreductase	HEK-293	0 CLOSED
25	A multiple ascending dose study evaluating the safety and gene transduction into malignant cells after administration of E1A-lipid complex by intratumoral injection with unresectable or metastatic head and neck tumours.	Head and Neck	Royal London Hospital; Charing Cross Hospital	Submission withdrawn	Plasmid	E1A	HEK293	Submission withdrawn

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26	A study of dose requirements, safety and local efficacy of intratumoral injection of the genetically modified non-virulent herpes simplex virus HSV ICP 34.5 negative mutant 1716 into accessible soft tissue nodules of secondary malignant melanoma.	Malignant Melanoma	Glasgow Western Infirmary and Southern General Hospital, Glasgow	9-98	HSV	ICP34.5 deleted	BHK-21/C13	5 CLOSED
27	The use of MetXia-P450 for the treatment of advanced breast cancer (Phase I/II intratumoral).	Breast Cancer	The Churchill Oxford	10-98	Retrovirus	Cytochrome P450	TEFLY-A	12 CLOSED
28	A phase I/II study of hepatic artery infusion with WTP53-CMV-AD in primary metastatic malignant liver tumours.	Liver Cancer	Hammersmith Hospital, London	Application Withdrawn	Adenovirus	p53	HEK293	Application withdrawn
29A	A Phase I/II pilot study of idiotypic vaccination for follicular B-cell lymphoma using a genetic approach	B-cell lymphoma	Royal Bournemouth Hospital; Southampton General Hospital; Christie Hospital Manchester	5-99	Plasmid	Idiotypic DNA vaccination	<i>E. coli</i> JM109	25 of 25 Under review to extend numbers
29B	A pilot study of donor idiotypic vaccination for the purpose of targeted post-	Multiple myeloma	Southampton General Hospital; Nottingham City Hospital; University College London	5-00	Plasmid	Idiotypic DNA vaccination	<i>E. coli</i> JM109	3 of 15

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	transplant immunotherapy following allogeneic bone marrow transplantation for multiple myeloma "EDLI"							
29C	Phase I/II study of idiotypic vaccination for multiple myeloma using a genetic approach (MMIFTT)	Multiple myeloma	Royal Bournemouth Hospital; Southampton General Hospital; Nottingham City Hospital	4-00	Plasmid	Idiotypic DNA vaccination	<i>E. coli</i> JM109	2 of 15 - 20
29D	Phase I/II study of idiotypic vaccination for chronic lymphocytic leukaemia using a genetic approach (CLLIFTT)	Chronic lymphocytic leukaemia	Royal Bournemouth Hospital; Southampton General Hospital	4-00	Plasmid	Idiotypic DNA vaccination	<i>E. coli</i> JM109	2 of 10 CLOSED
30	Use of a retrovirus carrying human cytochrome p450 for the treatment of ovarian cancer (Phase I intra-abdominal).	Ovarian Cancer	Northern General Hospital, Sheffield	2-00	Retrovirus	Cytochrome P450	TEFLY-A	6 CLOSED
31	Gene directed enzyme prodrug therapy for the treatment of head and neck cancer (Phase I intratumoral)	Head and Neck Cancer	Queen Elizabeth Hospital, Birmingham; Royal Marsden Hospital, London	7-99	Adenovirus	Nitroreductase	PER-C6	7 of 30 CLOSED
32	Gene directed enzyme prodrug therapy for the treatment of liver cancer (Phase I	Liver Cancer	Queen Elizabeth Hospital, Birmingham	7-99	Adenovirus	Nitroreductase	Per-c6	25 of 30

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	intratumoral)							
33	Phase I trial of immunotherapy with adenovirus-interferon- γ in malignant melanoma (intratumoral)	Malignant Melanoma	St. George's Hospital	7-99	Adenovirus	IFN- γ	-	1 CLOSED
34	A phase II/III trial of chemotherapy alone versus chemotherapy plus Adp53 in ovarian and primary intraperitoneal cancer (intraperitoneal)	Ovarian Cancer	Royal Marsden Hospital, Christie Hospital/ CRC Institute for Cancer Studies, John Radcliffe Hospital	7-99	Adenovirus	p53	HEK293	1 CLOSED
35	Phase II trial of pre-operative intratumoral injection with an E1B attenuated adenovirus in patients with resectable head and neck tumours	Head and Neck Cancer	Beatson Oncology Centre, Glasgow	7-99	Adenovirus	E1B deleted	HEK293	15 CLOSED
36	The safety and effects of Ad5.1 mediated human FGF-4 gene transfer in patients with peripheral arterial occlusive disease (PAOD)	Peripheral Arterial Occlusive Disease	St George's Hospital, London	10-00	Adenovirus	FGF-4	PER-C6	4 of 30 CLOSED

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37	A Phase III study of quadruple HAART followed by double-blind randomisation to HIV vaccination with ALVAC-HIV and Remune or placebo	HIV	Chelsea & Westminster Hospital, Royal Free Hospital, Brighton General Hospital, University Hospital of Wales Cardiff	5-00	Canarypox	HIV-1 <i>env</i> , <i>gag</i>	AVIAN	8 of 15 CLOSED
38	A Phase I, open label, dose escalation trial to assess the safety and immunogenicity of DISC-GMCSF in patients with metastatic melanoma	Malignant melanoma	Churchill Hospital, Oxford Royal Marsden Hospital, London	5-00	HSV	hGMCSF	CR2C9 (Vero-derived)	10 CLOSED
39	Gene therapy protocol for the evaluation of the safety, biodistribution and efficacy of TroVax in patients with metastatic colorectal cancer (Phase I i.m.)	Colorectal cancer	Christie Hospital NHS Trust, Manchester	10-00	Vaccinia	Human oncofoetal antigen 5T4	CEF	22 of 22 CLOSED
40	A Phase I dose escalation trial of an E1B attenuated adenovirus as an intravesical therapy for recurrent superficial/muscle invasive bladder cancer	Bladder cancer	St James's University Hospital, Leeds	Conditional Approval 7-00	Adenovirus	E1B deleted	HEK293	Trial not yet open for recruitment
41	Randomised multi-centre trial evaluating	Breast cancer	Guy's Hospital, London	Application withdrawn	Vaccinia	MUC-1, IL-2	CEF	Application withdrawn

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	two different vaccination schedules of MVA-MUC-1-IL-2 in women with metastatic breast cancer (Phase II i.m.)							
42	Phase I study of melanoma poly-epitope DNA and melanoma poly-epitope modified vaccinia Ankara in patients with melanoma	Melanoma	The Churchill Hospital, Oxford	7-00	Vaccinia DNA	Mel3 (melanoma antigens)	CEF	5 of 20
43	A phase I/II trial of polyHER2neu-a polyepitope DNA vaccine encoding HER-2 epitopes in the treatment of epithelial cancers (i.m.)	Breast cancer	St James's University Hospital, Leeds	Application Declined	Plasmid	HER-2 epitopes	<i>E. coli</i>	Application Declined
44	Treatment of leukaemic relapse after allogenic stem cell transplantation by HSV-tk transduced donor lymphocyte transfusions.	Chronic myeloid leukaemia	Hammersmith Hospital, London	10-00	Retrovirus	HSV -tk	AM12	0 of 10-20
45	Phase I clinical gene therapy protocol for X-SCID	X-SCID	Institute of Child Health, London	01-01	Retrovirus	Common gamma chain	PG13	7 of 20
46	Phase I gene therapy protocol for X-CGD	X-CGD	Institute of Child Health, London	12-00	Retrovirus	Gp91-phox	HEK293	3 of 5

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47	A phase I, Randomised, Double-blind, Placebo Controlled, Escalating Dose, Multicentre Study of Ad2/Hypoxia Inducible Factor Gene Transfer Administered by Intramyocardial Injection During Coronary Artery Bypass Grafting Surgery in Patients with Incomplete Revascularisation	Coronary artery disease	John Radcliffe Hospital, Oxford; King's College Hospital, London	12-00	Adenovirus	HIF-1 α /VP16	HEK293	9 of 12
48	A randomised phase I trial of intravenous CI-1042 with or without entanercept in patients with metastatic carcinoma	Metastatic carcinoma	Hammersmith Hospital, London	12-00	Adenovirus	p53	HEK293	Application withdrawn
49	A phase I/II Study of Immunotherapy for Patients with Metastatic Melanoma Using Dendritic Cells Transfected with a Plasmid Encoding Two Melanoma Antigens	Metastatic Melanoma	CRC Institute for Cancer Studies, Birmingham	02-01	Plasmid complexed with peptide	MART-1 gp-100	<i>E. coli</i>	Trial never opened CLOSED
50	A Phase II Trial of Preoperative intratumoural Injection	Head and Neck Cancer	Southern General Hospital, Glasgow	05-01	HSV	ICP34.5 deleted	BHK-21/C13	20 of 20 CLOSED

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	with HSV1716 in Patients with Resectable Squamous Cell Tumours of the Head and Neck							
51	A multinational multicenter, randomised, double-blind, placebo controlled study to evaluate the efficacy and safety of Ad5FGF-4 in patients with stable angina	Coronary Artery Disease	Papworth Hospital NHS Trust; Royal Sussex County Hospital; Royal Infirmary of Edinburgh; Hammersmith Hospital, London; King's College Hospital, London; Royal Free Hospital, London; St Thomas' Hospital, London; The London Chest Hospital; Wythenshawe Hospital, Manchester; Nottingham City Hospital; University Hospital Wales, Cardiff; Queen Elizabeth Hospital, Birmingham (to be confirmed)	05-01	Adenovirus	FGF-4	HEK293	17 of 60 in UK 116 of 450 world-wide CLOSED
52	A phase I study to evaluate the safety, tolerability and immunogenicity of two administrations of either plasmid DNA (pSG.HBs) versus placebo or modified vaccinia virus Ankara (MVA.HBs) versus	Hepatitis B Vaccine Trial	TNO BIBRA International, Surrey; University of Oxford; Central Middlesex Hospital	08-01	Vaccinia & plasmid	HBsAg	MVA: Chicken embryo fibroblasts; Plasmid in <i>E. coli</i>	18 of 18 CLOSED

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	placebo, followed by two boost administrations of MVA.HBs expressing hepatitis B surface antigen in healthy male volunteers							
53	A pilot study of the safety and immunogenicity of a candidate HIV-1 clade A DNA vaccine, pTHr.HIVA, given by needle injection into the deltoid muscle in HIV-1-seropositive subjects receiving highly active anti-retroviral therapy	AIDS	John Radcliffe Hospital, Oxford	05-01	Plasmid	HIV-1 clade A <i>gag</i> and 25 HIV-1 <i>gag</i> , <i>pol</i> , <i>env</i> , <i>nef</i> CTL epitopes	I DH1	10 of 10 CLOSED
54	A Phase II, Randomised, double-blind, Placebo-controlled, Parallel Group, Efficacy and Safety Study of NV1FGF in Patients with Severe Peripheral Artery Occlusive Disease	Peripheral Artery Occlusive Disease	St. George's Hospital, London; Royal Bournemouth Hospital; Leicester Royal Infirmary; Wythenshawe Hospital, Manchester; Freeman Hospital, Newcastle; Royal Free Hospital, London; Bristol Royal Infirmary (CLOSED); Leeds General Infirmary; Southampton General Hospital	08-01	Plasmid	FGF-1	I XAC-1	11 CLOSED
55	Gene directed enzyme	Prostate Cancer	Queen Elizabeth	04-01	Adenovirus	Nitro	PER-C6	32 of 44

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	prodrug therapy for the treatment of prostate cancer (Phase I intratumoral)		Hospital, Birmingham; Freeman Hospital Newcastle; St James's University Hospital, Leeds			reductase		
56	A Phase II, Multicentre, double-blinded, Placebo-Controlled, Dose-Finding Study of ZYC101a in the Treatment of high-grade Squamous Intra-Epithelial Lesions of the Uterine Cervix.	Ano-genital Neoplasia III	Hammersmith Hospital, London	11-01	Plasmid	HPV E6 & E7	<i>E. coli</i>	0 of 5 CLOSED
57	A Phase I, Multidose Study to Evaluate the Safety of Intramuscular Injections of HER-2 DNA in Patients with Metastatic Breast Cancer.	Breast Cancer	Hammersmith Hospital, London	11-01	Plasmid	HER-2	<i>E. coli</i>	27 of 27 CLOSED
58	The Use of a cDNA Vaccine Encoding the Human MUC1 Gene in the Treatment of Patients with Advanced Breast Cancer – A Phase I/II Study	Breast Cancer	ICRF, Guy's Hospital, London	08-01	Plasmid	MUC-1	<i>E. coli</i>	1 of 12-28
59	A phase IIa, open label trial to assess	Cervical Cancer	University of Wales, Cardiff; St. Mary's	07-01	Vaccinia	E6 & E7 HPV	MR-5	29 CLOSED

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	the safety, immunogenicity and efficacy of a prime-boost strategy of TA-CIN administered in associated with TA-HPV to patients with high grade ano-genital intraepithelial neoplasia (AGIN)		Manchester; Addenbrooke's, Cambridge.					
60	Study of Transfection Efficacy and Safety of MetXia-OB83 in patients with cutaneous lesions of breast cancer or melanoma	Breast Cancer	Churchill Hospital, Oxford; Queen Elizabeth Hospital, Birmingham	07-01	Retrovirus	P450	TEFLYRD	8 of 8 CLOSED
61	An upward titration study of transfection efficacy and safety of Metxia-OB83 in patients with adenocarcinoma of the prostate	Prostate Cancer	The Churchill Hospital, Oxford.	08-01	Retrovirus	P450	TEFLYRD	CLOSED
62	First Administration to Man of an Oncolytic Herpesvirus Vector Containing a Transgene for Granulocyte Macrophage Colony Stimulating Factor (OncoVex ^{GM-CSF}) – A	Melanoma, Breast, Head & Neck, cancer, Non-Hodgkins Lymphoma	Hammersmith Hospital, London; St George's Hospital, London; CR-UK Institute for Cancer Studies, University of Birmingham	11-01	HSV	ICP34.5-deleted ICP47-deleted Human GM-CSF	BHK 21c13	30 CLOSED

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	Study of its Safety, Biodistribution and Biological Activity.							
63	VTP-1/01: A Phase I/II Trial of Intravenous vs. Hepatic Arterial Infusion of an E1A-CR2 Deleted Adenovirus (VTP-1) in Patients with Inoperable, Metastatic Colorectal Carcinoma.	Metastatic colorectal carcinoma	Hammersmith Hospital, London	Application withdrawn	E1A conserved region 2 deleted & E3B RID gene region deleted	N/a	HEK-293	Application withdrawn
64	A Phase I trial of replication-competent herpes simplex virus (ICP 34.5 null mutant 1716) in patients with inoperable malignant pleural mesothelioma.	Malignant pleural mesothelioma	University of Glasgow, Beatson Oncology Centre, Glasgow	02-02	HSV HSV1716	ICP34.5 deleted	BHK-21/C13	0 CLOSED
65	A Phase I trial of PolyMEL, a polyepitope DNA vaccine in the treatment of metastatic melanoma patients.	Melanoma	St James Hospital, Leeds	01-02	Plasmid DNA (polyMEL)	Multiple melanoma epitopes	<i>E. coli</i>	1 of 12
66	A recombinant vaccinia Ankara (MVA)-based vaccine encoding Epstein-Barr Virus target antigens: phase I dose	Naso-Pharyngeal carcinoma	Institute of Cancer Studies, Birmingham	02-02	DNA plus MVA	EBV epitopes (EBNA1 and LMP2A)	CEF	0 of 12-15 Trial due to open in early 2005

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	escalation trial to determine immunogenicity and toxicity in patients with EBV+ malignancy EuraCT: 2004-001931-46							
67	Percutaneous Intramyocardial Gene Therapy against myocardial ischaemia with phVEGF-A165SR – A double-blind placebo controlled study	Coronary Artery Disease	Wythenshawe Hospital, Manchester	Application Pending	plasmid	VEGF	<i>E. coli</i>	Application withdrawn
68	A Phase I trial of polyHER2neu – a polyepitope DNA vaccine encoding HER-2 epitopes in the treatment of breast cancer.	Breast Cancer	St James Hospital, Leeds	01-02	Plasmid DNA	Poly epitopes of HER-2	<i>E. coli</i>	0 of 12 Trial not yet open
69	A phase I/II study of vaccination with a DNA fusion gene containing an epitope of CMV in allograft donors and patients awaiting renal transplantation	CMV infection following transplant	Southampton General Hospital; Royal Free Hospital London; University College London Hospital	02-02	Plasmid DNA (pcDNA3)	Peptide from pp65 from CMV	<i>E. coli</i>	4 of 15 pairs
70	NUMBER NOT ALLOCATED							
71	A Phase I/II	Glioma	University of Liverpool	Application	Replication	Human	Baby hamster	Trial

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	prospective study of immunogene therapy with a liposomally encapsulated replication incompetent Semliki Forest Virus (SFV) vector carrying the human interleukin-12 gene and administered intratumorally in patients with recurrent or progressing glioblastoma multiforme.			withdrawn	disabled Semliki Forest Virus, liposome encapsulated	IL-2	kidney (BHK)	withdrawn
72	Phase I/II study to determine the optimum dose and dosing regimen then to assess the efficacy of a poly-epitope pharmaccine, involving pSG2.Mel3 and MVA.Mel3, in patients with Stage III or Stage IV metastatic melanoma	Metastatic melanoma	Christie Hospital, Manchester; Churchill Hospital Oxford; Western General, Edinburgh; Southampton General Hospital	09-02	DNA and MVA	Multiple melanoma epitopes	CEF	36 of 41
73	Phase I clinical gene therapy protocol for adenosine deaminase deficiency	Severe Combined Immunodeficiency	Great Ormond Street Hospital, London	12-02	Retrovirus (spleen focus forming virus)	Adenosine Deaminase	PG13	1 of 5

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74	A Randomised Efficacy Trial of Herpes Simplex Virus HSV1716 in Recurrent Glioblastoma Multiforme (EudraCT: 2004-000097-32)	Glioblastoma multiforme	Queen Elizabeth Hospital, Birmingham; Southern General Hospital, Glasgow	07-04	HSV	ICP34.5 deleted	BHK21.c13	0 of 100 Trial not yet open for recruitment
75	A Phase I study of NYVAC C in healthy volunteers at low risk of HIV infection (EV01)	HIV-1	Imperial College London	02-03	MVA	HIV-1 Clade C <i>gag, pol, nef, env</i> , (NYVAC C)	Chick Embryo Fibroblasts	12 of 12 CLOSED
76	A phase I/II study of DNA vaccination with a CEA/pDOM fusion gene in patients with carcinoma expressing CEA	Carcinoma	Southampton General Hospital	02-03	Plasmid DNA (pcDNA3)	CAP-1 peptide from CEA	<i>E. coli</i>	0 of 30 Trial not yet open
77	Gene therapy protocol for the evaluation of the safety and efficacy of TroVax in conjunction with chemotherapy in patients with metastatic colorectal cancer	Metastatic colorectal cancer	Christie Hospital Manchester; Queen Elizabeth Hospital, Birmingham	02-03	MVA	Human Oncofoetal Antigen 5T4	Chick Embryo Fibroblasts	19 of 19 CLOSED to recruitment
78	A phase I clinical gene therapy trial for X-SCID using umbilical cord blood	X-SCID	Institute of Child Health, London	02-03	Retrovirus (Moloney murine leukaemia virus)	Common gamma chain	PG13	0 of 10
79	A pilot study to	HIV-1	MRC Human Immunology	07-03	MVA	HIV-1	CEF	10 of 20

GTAC NO.	PROTOCOL NAME	DETAILS	CENTRE	OUTLINE APPROVAL	VECTOR	GENE	CELL LINE	NO. OF PATIENTS
	evaluate the safety, tolerability and immunogenicity of a candidate HIV-1 vaccine, MVA.HIVA delivered to HIV-1 sero-positive adults receiving HAART		Unit, John Radcliffe Hospital, Oxford			clade A <i>gag, pol, nef</i> and <i>env</i>		Closed to new recruitment
80	Phase I/II study – first administration of Dendritic cells transduced with ImmunoVEX ^{TRI-Melan} to patients with metastatic or inoperable melanoma	metastatic or inoperable melanoma	St George's Hospital Medical School, London	Application declined	HSV	hTyrosinase, hMART1, hGP100	Vero (MEVP16/M4 F6A)	Application declined
81	An open label study of TroVax given in conjunction with 5-Fluorouracil/Leukovorin/Oxaliplatin: safety and immunogenicity before, during and after chemotherapy (TV2)	Colorectal cancer	University of Leeds School of Medicine; Hammersmith Hospital, London	05-03	MVA	Human oncofoetal antigen 5T4	CEF	17 of 17 CLOSED to recruitment
82	A phase II trial to evaluate efficacy and safety of intramuscular injections of HER-2 DNA Autovac TM in patients with metastatic or locally	Breast cancer	Hammersmith Hospital	07-03	Plasmid	HER-2 with T cell epitopes P2 and P30 derived from	<i>E. coli</i>	Trial withdrawn

GTAC NO.	PROTOCOL NAME	DETAILS	CENTRE	OUTLINE APPROVAL	VECTOR	GENE	CELL LINE	NO. OF PATIENTS
	advanced breast cancer					tetanus toxin		
83	A Phase I/II safety study of MetXia-OB83 in patients with pancreatic cancer	Pancreatic cancer	Royal Liverpool University Hospital, Leicester Royal Infirmary; Christie Hospital, Manchester	10-03	Retrovirus (Moloney murine leukaemia virus)	cytochrome P450	FLY RD83	3 of 27
84	A Phase I study of immunotherapy for patients with metastatic melanoma using dendritic cells transfected with a plasmid encoding two melanoma antigens	Malignant melanoma	CRUK, Birmingham	07-03	Plasmid DNA	MART-1 and gp-100	<i>E. coli</i>	9 of 10
85	A phase I trial to assess the safety of DNA C, and the safety and immunogenicity of DNA C followed by NYVAC C in an open, randomised comparison to NYVAC C alone in healthy volunteers at low risk of HIV infection (EV02) (EudraCT: 2004-001802-28)	HIV-1	Imperial College London, St's Mary's Hospital	10-03	Plasmid pORT1	HIV-1 clade C <i>gag, pol, nef, env</i>	<i>E. coli</i>	0 of 20 Trial due to open in early 2005
86	First administration of dendritic cells transduced with ImmunoVEX ^{Tri-Melan} to	metastatic or inoperable melanoma	St George's Hospital Medical School, Southampton General Hospital	10-03	HSV	hTyrosinase, hMART1, hGP100	Vero (MEVP16/M4 F6A)	0 of 60 Enrolment not yet started.

GTAC NO.	PROTOCOL NAME	DETAILS	CENTRE	OUTLINE APPROVAL	VECTOR	GENE	CELL LINE	NO. OF PATIENTS
	patients with metastatic or inoperable melanoma, preliminary assessment of safety, biodistribution and indicators of efficacy							
87	A Phase II Study Immunologically Evaluating 5T4-MVA (TroVax) in Patients undergoing Surgical Resection of Colorectal Liver Metastases	Metastatic colorectal cancer	Christie Research Centre, Manchester; North Manchester General Hospital	01-04	MVA	Human Oncofoetal Antigen 5T4	Chick Embryo Fibroblasts	10 of 20
88	A Cancer Research UK Phase I Trial of AEG35156/GEM640 (XIAP antisense) administered as a 7 day continuous intravenous infusion in patients with advanced tumours	advanced tumours	Christie Hospital NHS Trust, Edinburgh Royal Infirmary	12-03	N/a	Antisense DNA to human X-linked inhibitor of apoptosis	N/a	11 of 18-40
89	A Phase I/II Trial of a DNA vaccine with a PSMA ₂₇ / pDom fusion gene given by intramuscular injection in HLA A2+ patients with prostate carcinomas with or without electroporation	Prostate cancer	Southampton General Hospital; Royal Marsden Hospital, London	02-04	DNA with and without electroporation	1 st domain of Tetanus toxin fragment C, 9 amino acid peptide from PSMA	<i>E. coli</i>	- of 30. Trial not yet open

GTAC NO.	PROTOCOL NAME	DETAILS	CENTRE	OUTLINE APPROVAL	VECTOR	GENE	CELL LINE	NO. OF PATIENTS
90	A Controlled, Randomised, Parallel Group, Multicentre Study of the Efficacy and Safety of Herpes Simplex Virus-Thymidine Kinase Gene Therapy (Cerepro™), with Subsequent Ganciclovir, for the Treatment of Patients with Operable High Grade Glioma	Operable primary or recurrent high grade glioma	Walton Centre for Neurology and Neurosurgery, Liverpool; Western General Hospital, Edinburgh; Addenbrooks Hospital, Cambridge; Queen's Medical Centre, Nottingham; Hope Hospital, Salford	04-04	Adenovirus type 5, E1 and E3 deleted	Herpes simplex virus-thymidine kinase gene (HSV-tk)	HEK293	Target: 250 world-wide 50 in UK Start of trial: early 2005
91	Double-blind, randomised, placebo-controlled, parallel group and dose-finding, multicentric, safety and efficacy study with intramuscular injections of NV1FGF in subjects with intermittent claudication	Peripheral artery occlusive disease in patients with intermittent claudication	Royal Bournemouth Hospital; Freeman Hospital Newcastle; Gloucestershire Royal Hospital	03-04	Plasmid	FGF-1	<i>E coli</i> XAC-1	Total of 360 world-wide
92	A 2 x 2 Factorial Randomised Phase II Trial Assessing Anti-CEA, Anti-MUC-1 Vaccination +/- Chemotherapy +/- GM-CSF after Surgery	Colorectal Cancer	Churchill Hospital, Oxford	06-04	Vaccinia and fowlpox virus,	carcinoembryonic antigen, Mucin-1, B7-1, ICAM-1 and LFA-3		- of 40

GTAC NO.	PROTOCOL NAME	DETAILS	CENTRE	OUTLINE APPROVAL	VECTOR	GENE	CELL LINE	NO. OF PATIENTS
	in Patients with Stage II Colorectal Cancer. (EudraCT: 2004-001734-16)							
93	An open, randomised, parallel group study to evaluate the safety, tolerability and immunogenicity of the GW825780 DNA immunotherapeutic when delivered using the PowderJect ND5.5 device to healthy adult volunteer subjects. (EudraCT: 2004-000251-41)	HIV	Addenbrooke's Hospital Cambridge; Chiltern International, Slough	06-04	Plasmid on gold particles	Reverse transcriptase, nef, gag of HIV-1	E. coli DH1	37 Closed to recruitment
94	A Phase II exploratory study of the efficacy and safety of OncoVEX GM-CSF in combination with Arimidex in the neoadjuvant treatment of breast cancer in post menopausal women with oestrogen receptor positive tumours (EudraCT: 2004-01938-16)	Breast Cancer	Hammersmith Hospitals NHS Trust	Application declined	HSV	ICP34.5-deleted ICP47-deleted Human GM-CSF	BHK 21c13	- of 20
95	Safety and immunology evaluation of TroVax	Colorectal cancer	Christie Research Centre, Manchester; University of Leeds School of Medicine	11/04	MVA	Human Oncofoetal Antigen	Chick Embryo Cells	0 of 10 Trial not yet open

GTAC NO.	PROTOCOL NAME	DETAILS	CENTRE	OUTLINE APPROVAL	VECTOR	GENE	CELL LINE	NO. OF PATIENTS
	produced by the Baxter synthetic route in patients with stage IV colorectal cancer (EudraCT: 2004-002251-13)					5T4		
96	A Phase I Study of Adoptive Transfer of Autologous Tumour Antigen-Specific T Cells with Pre-conditioning Chemotherapy and Intravenous IL2 in Patients with Advanced CEA Positive Tumours	CEA positive malignancies	Christie Research Centre, Manchester	11-04	Retrovirus	MFE23 specific for carcinoembryonic antigen; CD3 ζ	Murine PG13	- 15
97	A multicenter, randomised, double-blind, placebo-controlled study evaluating the efficacy of BIOBYPASS (ADGVVEGF121.10N H) delivered by NOGATM - Guided/myostar catheter in no option patients with class II-IV stable angina. EudraCT: 2004-002449-10	Stable angina	King's College Hospital, Southampton University Hospital	11-04	Adenovirus type 5	VEGF	human embryonic retinoblasts (PER.C6)	- of 129
98	A pilot study of	Acute myeloid	King's College London	11-04	Lentivirus	CD80	human	- of 10

GTAC NO.	PROTOCOL NAME	DETAILS	CENTRE	OUTLINE APPROVAL	VECTOR	GENE	CELL LINE	NO. OF PATIENTS
	lentivirus transduced acute myeloid leukaemia (AML) blasts expressing B7.1 (CD80) and IL-2, for the induction of graft verses leukaemia (GVL) effect in poor prognosis, relapsed AML	leukaemia			(HIV-1)	(B7.1) and IL-2	embryonic kidney 293T	
99	A Phase 2, Randomized, Double-blind, Placebo controlled, Parallel-group, Multicenter, Dose-Selection Study of Ad2/Hypoxia Inducible Factor HIF-1 α /VP16 in Patients with Intermittent Claudication. EudraCT: 2004-002508-13	Peripheral artery disease: Intermittent Claudication	Ninewells Hospital, Dundee;	11-04	Adenovirus (E1 and E4 deleted)	HIF-1 α (Hypoxia-Inducible Factor-1)	human 293 cells	- of 75