

New Active Substances (NASs) approved by six major authorities in 2019

Prepared by:

Céline Rodier, PharmD, Senior Research Analyst

Magdalena Bujar, PhD, MSc, Manager, Strategic Development

Neil McAuslane, PhD, Scientific Director

Lawrence Liberti, PhD, RPh, RAC, Head, Regulatory Collaborations

Jamie W. Munro, BSc, PhD, Executive Director

Centre for Innovation in Regulatory Science (CIRS)

Friars House
160 Blackfriars Road
London
SE1 8EZ
UK

Email: cirs@cirsci.org

Website: www.cirsci.org

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EMA NAS approvals in 2019



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan	Exceptional Circumstances	Conditional Approval	PRIME designation
Macimorelin Aeterna Zentaris	Macimorelin Acetate	Aeterna Zentaris GmbH	11-Jan-2019				N	
Erleada	Apalutamide	Janssen-Cilag International N.V	14-Jan-2019				N	
Besremi	Ropeginterferon Alfa-2b	AOP Orphan Pharmaceuticals AG	15-Feb-2019				N	
Mulpleo (Previously Lusutrombopag Shionogi)	Lusutrombopag	Shionogi B.V.	18-Feb-2019				N	
Rizmoic	Naldemedine Tosilate	Shionogi B.V.	18-Feb-2019				N	
Ajovy	Fremanezumab	Teva GmbH	28-Mar-2019				N	
Vizimpro	Dacomitinib Monohydrate	Pfizer Europe MA EEIG	2-Apr-2019				N	
Ondexxya	Andexanet Alfa	Portola Netherlands B.V.	26-Apr-2019					
Skyrizi	Risankizumab	AbbVie Deutschland GmbH & Co. KG	26-Apr-2019				N	
Zynquista	Sotagliflozin	Sanofi-aventis groupe	26-Apr-2019				N	
Palyzniq	Pegvaliase	BioMarin International Limited	3-May-2019				N	
Waylivra	Volanesorsen Sodium	Akcea Therapeutics Ireland Limited	3-May-2019					
Lorviqua	Lorlatinib	Pfizer Europe MA EEIG	6-May-2019					
Zynteglo	Autologous Cd34+ Cell Enriched Population That Contains Hematopoietic Stem Cells Transduced With Lentiglobin Bb305 Lentiviral Vector Encoding The Beta-A-T87q-Globin Gene	bluebird bio (Netherlands) B.V.	29-May-2019					
Esperoct	Turoctocog Alfa Pegol	Novo Nordisk A/S	20-Jun-2019				N	
Doptelet	Avatrombopag	Dova Pharmaceuticals Ireland Limited	20-Jun-2019				N	
Talzenna	Talazoparib	Pfizer Europe MA EEIG	20-Jun-2019				N	
Libtayo	Cemiplimab	Regeneron Ireland U.C.	28-Jun-2019					
Ultomiris	Ravulizumab	Alexion Europe SAS	2-Jul-2019				N	
Giapreza	Angiotensin II acetate	La Jolla Pharmaceutical II B.V.	23-Aug-2019				N	

*Expedited review refers to EMA Accelerated Assessment



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan	Exceptional Circumstances	Conditional Approval	PRIME designation
Vitrakvi	larotrectinib sulfate	Bayer AG	19-Sep-2019					
Trogarzo	Ibalizumab	Theratechnologies International Limited	26-Sep-2019				N	
Xospata	Gilteritinib fumarate	Astellas Pharma Europe B.V.	24-Oct-2019				N	
Rhokiinsa	Netarsudil	Aerie Pharmaceuticals Ireland Ltd	19-Nov-2019				N	
Evenity	Romosozumab	UCB Pharma S.A.	9-Dec-2019				N	
Quofenix	Delafloxacin meglumine	A. Menarini Industrie Farmaceutiche Riunite s.r.l.	16-Dec-2019				N	
Rinvoq	Upadacitinib	AbbVie Deutschland GmbH & Co. KG	16-Dec-2019				N	

*Expedited review refers to EMA Accelerated Assessment

FDA NAS approvals in 2019



Brand Name	Generic Name	Marketing Authorization Holder	Approval Date	Expedited Review*	Orphan	Fast Track	Break-through	Accelerated Approval
Cablivi	Caplacizumab-Yhdp	AblynxNV	6-Feb-2019					
Egaten	Triclabendazole	Novartis Pharmaceuticals Corporation	13-Feb-2019					
Esperoct	Antihemophilic Factor (Recombinant), Glycopegylated-Exei	Novo Nordisk, Inc.	19-Feb-2019					
Spravato	Esketamine Hydrochloride	Janssen Pharmaceuticals, Inc.	5-Mar-2019					
Zulresso	Brexanolone	Sage Therapeutics, Inc.	19-Mar-2019					
Sunosi	Solriamfetol	Jazz Pharmaceuticals Ireland Limited	20-Mar-2019					
Mayzent	Siponimod Fumaric Acid	Novartis Pharmaceuticals Corporation	26-Mar-2019					
Evenity	Romosozumab-Aqqg	Amgen Inc.	9-Apr-2019					
Balversa	Erdafitinib	Janssen Biotech, Inc.	12-Apr-2019					
Skyrizi	Risankizumab-Rzaa	AbbVie, Inc.	23-Apr-2019					
Vyndaqel	Tafamidis Meglumine	FoldRx a wholly owned subsidiary of Pfizer, Inc.	3-May-2019					
Piqray	Alpelisib	Novartis Pharmaceuticals Corporation	24-May-2019					
Zolgensma	Onasemnogene Apeparovvec-Xioi	AveXis, Inc	24-May-2019					
Polivy	Polatuzumab Vedotin-Piiq	Genentech, Inc	10-Jun-2019					
Vyleesi (Autoinjector)	Bremelanotide Acetate	AMAG Pharmaceuticals, Inc	21-Jun-2019					
Xpovio	Selinexor	Karyopharm Therapeutics, Inc	3-Jul-2019					
Recarbrio	Cilastatin Sodium; Imipenem; Relebactam	Merck Sharp & Dohme Corp	16-Jul-2019					
Nubeqa	Darolutamide	Bayer HealthCare Pharmaceuticals Inc	30-Jul-2019					
Turalio	Pexidartinib Hydrochloride	Daiichi Sankyo, Inc.	2-Aug-2019					
Wakix	Pitolisant Hydrochloride	Bioprojet Pharma	14-Aug-2019					
Pretomanid	Pretomanid	The Global Alliance for TB Drug Development, Inc. (TB Alliance)	14-Aug-2019					
Rozlytrek	Entrectinib	Genentech, Inc	15-Aug-2019					
Inrebic	Fedratinib Hydrochloride	Impact Biomedicines, Inc., a Wholly-owned Subsidiary of Celgene Corporation	16-Aug-2019					
Rinvoq	Upadacitinib	AbbVie Inc	16-Aug-2019					
Xenleta	Lefamulin Acetate	Nabriva Therapeutics Ireland DAC	19-Aug-2019					
Nourianz	Istradefylline	Kyowa Kirin, Inc	27-Aug-2019					
Ibsrela	Tenapanor Hydrochloride	Ardelyx, Inc.	12-Sep-2019					
Aklief	Trifarotene	Galderma Research and Development, LLC	4-Oct-2019					

* Expedited review refers to FDA Priority Review

FDA NAS approvals in 2019



Brand Name	Generic Name	Marketing Authorization Holder	Approval Date	Expedited Review*	Orphan	Fast Track	Break-through	Accelerated Approval
Beovu	Brolucizumab-Dbll	Novartis Pharmaceuticals Corporation	7-Oct-2019					
Scenesse	Afamelanotide	Clinuvel Inc	8-Oct-2019					
Fluorodopa F 18	Fluorodopa F 18	The Feinstein Institute for Medical Research	10-Oct-2019					
Reyvow	Lasmiditan Succinate	Eli Lilly and Company	11-Oct-2019					
Trikafta (Copackaged)	Elexacaftor, Ivacaftor, Tezacaftor	Vertex Pharmaceuticals Inc	21-Oct-2019					
Exem Foam Kit	Air Polymer-Type A	GISKIT B.V.	7-Nov-2019					
Reblozyl	Luspatercept-Aamt	Celgene Corporation	8-Nov-2019					
Fetroja	Cefiderocol Sulfate Tosylate	Shionogi, Inc.	14-Nov-2019					
Brukinsa	Zanubrutinib	BeiGene USA, Inc.	14-Nov-2019					
Adakveo	Crizanlizumab-Tmca	Novartis Pharmaceuticals Corporation	15-Nov-2019					
Givlaari	Givosiran Sodium	Alnylam Pharmaceuticals Inc	20-Nov-2019					
Xcopri	Cenobamate	SK Life Science, Inc	21-Nov-2019					
Oxbryta	Voxelotor	Global Blood Therapeutics, Inc.	25-Nov-2019					
Vyondys 53	Golodirsen	Sarepta Therapeutics, Inc	12-Dec-2019					
Padcev	Enfortumab Vedotin-Ejfv	Astellas Pharma US, Inc	18-Dec-2019					
Dayvigo	Lemborexant	Eisai Inc	20-Dec-2019					
Caplyta	Lumateperone Tosylate	Intra-Cellular Therapies, Inc	20-Dec-2019					
Enhertu	Fam-Trastuzumab Deruxtecan-Nxki	Daiichi Sankyo, Inc	20-Dec-2019					
Ubrelyv	Ubrogepant	Allergan Sales, Inc	23-Dec-2019					

* Expedited review refers to FDA Priority Review

PMDA NAS approvals in 2019



Brand Name	Generic Name	Marketing Authorization Holder	Approval Date	Expedited Review*	Orphan	Sagikake	Conditional Early Approval
Mektovi	Binimetinib	Ono Pharmaceutical Co., Ltd	8-Jan-2019				
Zerbaxa Combination	Ceftolozane sulfate/Tazobactam sodium	MSD K.K	8-Jan-2019				
Vizimpro	Dacomitinib hydrate	Pfizer Japan Inc	8-Jan-2019				
Braftovi	Encorafenib	Ono Pharmaceutical Co., Ltd	8-Jan-2019				
Minnebro	Esaxerenone	Daiichi Sankyo Company, Limited	8-Jan-2019				
Demser	Metirosine	Ono Pharmaceutical Co., Ltd	8-Jan-2019				
Tarlige	Mirogabalin besilate	Daiichi Sankyo Company, Limited	8-Jan-2019				
Selincro	Nalmefene hydrochloride hydrate	Otsuka Pharmaceutical Co., Ltd	8-Jan-2019				
Relumina	Relugolix	Takeda Pharmaceutical Company Limited	8-Jan-2019				
Evenity	Romosozumab (genetical recombination)	Amgen Astellas BioPharma K.K	8-Jan-2019				
Epcusa Combination	Sofosbuvir/Velpatasvir	Gilead Sciences K.K.	8-Jan-2019				
Erleada	Apalutamide	Janssen Pharmaceutical K.K.	26-Mar-2019				
Biktarvy	Bictegravir sodium/ Emtricitabine/Tenofovir alafenamide fumarate	Gilead Sciences K.K.	26-Mar-2019				
Revcovi	Elapegedemase (genetical recombination)	Teijin Pharma Limited	26-Mar-2019				
Vyvanse	Lisdexamfetamine mesilate	Shionogi & Co., Ltd	26-Mar-2019				
Smyraf	Peficitinib hydrobromide	Astellas Pharma Inc	26-Mar-2019				
Privigen	pH4-treated acidic normal human immunoglobulin	CSL Behring K.K	26-Mar-2019				
Skyrizi	Risankizumab (genetical recombination)	AbbVie GK	26-Mar-2019				
Defitelio	Defibrotide sodium	Nippon Shinyaku Co., Ltd	18-Jun-2019				
Rozlytrek	Entrectinib	Chugai Pharmaceutical Co., Ltd	18-Jun-2019				
Portrazza	Necitumumab (genetical recombination)	Eli Lilly Japan K.K	18-Jun-2019				
Onpattro	Patisiran sodium	Alnylam Japan K.K	18-Jun-2019				
Vanflyta	Quizartinib hydrochloride	Daiichi Sankyo Company, Limited	18-Jun-2019				
Ultomiris	Ravulizumab (genetical recombination)	Alexion Pharma G.K	18-Jun-2019				
Crysvita	Burosumab (genetical recombination)	Kyowa Kirin Co., Ltd.	20-Sep-2019				

* Expedited review refers to PMDA Priority Review



Brand Name	Generic Name	Marketing Authorization Holder	Approval Date	Expedited Review*	Orphan	Sagikake	Conditional Early Approval
Brineura	Cerliponase alfa (genetical recombination)	BioMarin Pharmaceutical Japan	20-Sep-2019				
Coralan	Ivabradine hydrochloride	Ono Pharmaceutical Co., Ltd	20-Sep-2019				
Lasvic	Lascefloxacin hydrochloride	Kyorin Pharma Co., Ltd.	20-Sep-2019				
Evrenzo	Roxadustat	Astellas Pharma Inc	20-Sep-2019				
Equfina	Safinamide mesilate	Meiji Seika Pharma Co., Ltd.	20-Sep-2019				
Esperoct	Turoctocog alfa pegol (genetical recombination)	Novo Nordisk Co., Ltd.	20-Sep-2019				
Venclexta	Venetoclax	AbbVie GK	20-Sep-2019				
Trintellix	Vortioxetine hydrobromide	Takeda Pharmaceutical Company Limited	20-Sep-2019				

* Expedited review refers to PMDA Priority Review

Health Canada NAS approvals in 2019



Brand Name	Generic Name	Marketing Authorization Holder	Approval Date	Expedited Review*	Orphan**	Notice of Compliance with conditions (NOC/c)	ACSS worksharing
Lutathera	Lutetium (177Lu) Oxodotreotide	Advanced Accelerator Applications Usa, Inc	9-Jan-2019				
Onstryv	Safinamide	Valeo Pharma Inc	10-Jan-2019				
Demylocan	Decitabine	Pendopharm Division Of Pharmascience Inc	21-Jan-2019				
Idhifa	Enasidenib Mesylate	Celgene Inc	6-Feb-2019				
Oxervate	Cenegermin	Dompé Farmaceutici S-P-A-	8-Feb-2019				
Yescarta	Axicabtagene Ciloleucel	Gilead Sciences Canada Inc	13-Feb-2019				
Lorbrena	Lorlatinib	Pfizer Canada Ulc	22-Feb-2019				
Vizimpro	Dacomitinib	Pfizer Canada Inc	26-Feb-2019				
Verzenio	Abemaciclib	Eli Lilly Canada Inc	5-Apr-2019				
Libtayo	Cemiplimab	Sanofi-Aventis Canada Inc	10-Apr-2019				
Skyrizi	Risankizumab	Abbvie Corporation	17-Apr-2019				
Tibella	Tibolone	Biosyent Pharma Inc	10-May-2019				
Onpattro	Patisiran Sodium	Alnylam Netherlands B-V-	7-Jun-2019				
Evenity	Romosozumab	Amgen Canada Inc	17-Jun-2019				
Zejula	Niraparib	Glaxosmithkline Inc	27-Jun-2019				
Netspot	Gallium Ga 68 Dotatate	Advanced Accelerator Applications Usa, Inc-	3-Jul-2019				
Esperoct	Antihemophilic Factor VIII (Recombinant, B-Domain Truncated), Pegylated	Novo Nordisk Canada Inc	4-Jul-2019				
Vitrakvi	Larotrectinib	Bayer Inc	10-Jul-2019				
Nerlynx	Neratinib Maleate	Puma Biotechnology Inc	16-Jul-2019				
Lokelma	Sodium Zirconium Cyclosilicate	Astrazeneca Canada Inc	25-Jul-2019				
Emgality	Galcanezumab	Eli Lilly Canada Inc	30-Jul-2019				
Calquence	Acalabrutinib	Astrazeneca Canada Inc	23-Aug-2019				
Ultomiris	Ravulizumab	Alexion Pharma Gmbh	28-Aug-2019				
Talzenna	Talazoparib	Pfizer Canada Ulc	6-Sep-2019				

*Expedited review refers to Health Canada Priority Review

**Health Canada does not have an orphan policy

Health Canada NAS approvals in 2019



Brand Name	Generic Name	Marketing Authorization Holder	Approval Date	Expedited Review*	Orphan**	Notice of Compliance with conditions (NOC/c)	ACSS worksharing
Trulance	Plecanatide	Cipher Pharmaceuticals Inc	10-Oct-2019				
Balversa	Erdafitinib	Janssen Inc	25-Oct-2019				
Aklief	Trifarotene	Galderma Canada Inc	25-Nov-2019				
Mylotarg	Gemtuzumab Ozogamicin	Pfizer Canada Ulc	28-Nov-2019				
Xospata	Gilteritinib Fumarate	Astellas Pharma Canada Inc	23-Dec-2019				
Rinvoq	Upadacitinib	Abbvie Corporation	23-Dec-2019				

*Expedited review refers to Health Canada Priority Review

**Health Canada does not have an orphan policy



Brand Name	Generic Name	Marketing Authorization Holder	Approval Date	Expedited Review*	Orphan	Procedure with prior notification (VmVA)	Conditional approval	Art.13 TPA	ACSS worksharing
Radicava, Infusionslösung	Edaravonum	Mitsubishi Tanabe Pharma Gmbh	31-Jan-2019						
Spherox, Suspension Zur Implantation	Autologous Cultured Chondrocytes	Co.Don Schweiz Gmbh	27-Mar-2019						
Emgality, Solution Pour Injection En Stylo Pré-Rempli	Galcanezumabum	Eli Lilly (Suisse) Sa	29-Mar-2019						
Dupixent, Solution Injectable En Seringue Préremplie Avec Système De Sécurité	Dupilumabum	Sanofi-Aventis (Suisse) Sa	5-Apr-2019						
Biktarvy, Filmtabletten	Bictegravirum Natricum, Emtricitabinum And Tenofovir Alafenamidi Hemifumaras	Gilead Sciences Switzerland Sàrl	12-Apr-2019						
Yescarta	Axicabtagenum Ciloleucelum	Gilead Sciences Switzerland Sàrl	17-Apr-2019						
Skyrizi, Injektionslösung	Risankizumabum	Abbvie Ag	18-Apr-2019						
Ilumetri, Injektionslösung	Tildrakizumabum	Almirall Ag	18-Apr-2019						
Symdeko, Filmtabletten	Ivacaftorum And Tezacaftorum	Vertex Pharmaceuticals (Ch) Gmbh	10-May-2019						
Verzenios, Comprimés Filmés	Abemaciclibum	Eli Lilly (Suisse) Sa	21-May-2019						
Zavicefta, Pulver Für Ein Konzentrat Zur Herstellung Einer Infusionslösung	Avibactamum Natricum And Ceftazidimum Pentahydricum	Pfizer Pfe Switzerland Gmbh	5-Jun-2019						
Takhzyro, Injektionslösung	Lanadelumabum	Shire Switzerland Gmbh	6-Jun-2019						
Jivi, Pulver Und Lösungsmittel Zur Herstellung Einer Injektionslösung	Damoctocogum Alfa Pegolum	Bayer (Schweiz) Ag	18-Jun-2019						
Lutathera, Solution Pour Perfusion	Lutetium (177lu) Oxodotreotidum	Advanced Accelerator	25-Jun-2019						

*Expedited review refers to Swissmedic Priority Review



Brand Name	Generic Name	Marketing Authorization Holder	Approval Date	Expedited Review*	Orphan	Procedure with prior notification (VmVA)	Conditional approval	Art.13 TPA	ACSS worksharing
Esperoct, Pulver Und Lösungsmittel Zur Herstellung Einer Injektionslösung	Turoctocogum Alfa Pegolum	Novo Nordisk Pharma Ag	30-Jul-2019						
Procysbi, Gélules Gastro-Résistantes	Mercaptamini Bitartras	Chiesi Sa	16-Aug-2019						
Fampyra, Retardtabletten	Fampridinum	Biogen Switzerland Ag	22-Aug-2019						
Monofer, Lösung Zur Intravenösen Injektion/Infusion	Ferrum(Iii) (As Ferri Isomaltosidum 1000)	Pierre Fabre Pharma Sa	26-Aug-2019						
Vizimpro, Filmtabletten	Dacomitinibum Monohydricum	Pfizer Ag	27-Aug-2019						
Erleada, Filmtabletten	Apalutamidum	Janssen-Cilag Ag	19-Sep-2019						

*Expedited review refers to Swissmedic Priority Review

TGA NAS approvals in 2019



Brand Name	Generic Name	Marketing Authorization Holder	Approval Date	Expedited Review*	Orphan	Provisional Approval	ACSS worksharing
Pifeltro	Doravirine	Merck Sharp & Dohme (Australia) Pty Ltd	18-Jan-2019				
Xiidra	Lifitegrast	Shire Australia Pty Ltd	18-Jan-2019				
Takhzyro	Lanadelumab	Shire Australia Pty Ltd	24-Jan-2019				
Staquis	Crisaborole	Pfizer Australia Pty Ltd	15-Feb-2019				
Symdeko	Ivacaftor; Tezacaftor	Vertex Pharmaceuticals Australia Pty Ltd	1-Mar-2019				
Alunbrig	Brigatinib	Takeda Pharmaceuticals Australia Pty Ltd	4-Mar-2019				
Nerlynx	Neratinib Maleate	Specialised Therapeutics Pm Pty Ltd	14-Mar-2019				
Verzenio	Abemaciclib	Eli Lilly Australia Pty Ltd	8-Apr-2019				
Cresemba	Isavuconazole	Pfizer Australia Pty Ltd	15-May-2019				
Emgality	Galcanezumab	Eli Lilly Australia Pty Ltd	22-May-2019				
Constella	Linaclotide	Allergan Australia Pty Ltd	28-May-2019				
Evenity	Romosozumab	Amgen Australia Pty Ltd	21-Jun-2019				
Zejula	Niraparib (As Tosilate Monohydrate)	Takeda Pharmaceuticals Australia Pty Ltd	28-Jun-2019				
Skyrizi	Risankizumab	Abbvie Pty Ltd	15-Jul-2019				
Ozempic	Semaglutide (Rys)	Novo Nordisk Pharmaceuticals Pty Ltd	15-Aug-2019				
Refixia	Nonacog Beta Pegol	Novo Nordisk Pharmaceuticals Pty Ltd	2-Sep-2019				
Diacomit	Stiripentol	Emerge Health Pty Ltd	11-Sep-2019				
Oxervate	Cenegermine (Rbe)	Jace Pharma Pty Ltd	16-Sep-2019				
Ajovy	Fremanezumab	Teva Pharma Australia Pty Ltd	17-Sep-2019				
Ultomiris	Ravulizumab	Alexion Pharmaceuticals Australasia Pty Ltd	8-Oct-2019				
Polivy	Polatuzumab Vedotin	Roche Products Pty Ltd	21-Oct-2019				
Lorviqua	Lorlatinib	Pfizer Australia Pty Ltd	11-Nov-2019				
Talzenna	Talazoparib Tosilate	Pfizer Australia Pty Ltd	15-Nov-2019				
Increlex	Mecasermin	Ipsen Pty Ltd	19-Nov-2019				
Calquence	Acalabrutinib	Astrazeneca Pty Ltd	21-Nov-2019				

*TGA has introduced an expedited (priority) review programme in 2017.

Definitions

Approval time

Time calculated from the date of submission to the date of approval by the agency. This time includes agency and company time.

New Active Substances (NAS)

A chemical, biological, biotechnology or radiopharmaceutical substance that has not been previously available for therapeutic use in humans and is destined to be made available as a 'prescription only medicine', to be used for the cure, alleviation, treatment, prevention or in vivo diagnosis of diseases in humans. The term NAS also includes:

- An isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously available as a medicinal product but differing in properties with regard to safety and efficacy from that substance previously available
- A biological or biotech substance previously available as a medicinal product, but differing in molecular structure through changes to the nature of source material or manufacturing process and which will require clinical investigation
- A radiopharmaceutical substance that is a radionuclide or a ligand not previously available as a medicinal product. Alternatively, the coupling mechanism linking the molecule and the radionuclide has not been previously available

Applications that are excluded from the study

- Vaccines
- Biosimilars
- Any other application, where new clinical data were submitted
- Generic applications
- Those applications where a completely new dossier was submitted from a new company for the same indications as already approved for another company
- Applications for a new or additional name, or a change of name, for an existing compound (i.e., a 'cloned' application)

Report prepared by

Céline Rodier, PharmD, Senior Research Analyst
Magdalena Bujar, PhD, MSc, Manager, Strategic Development
Neil McAuslane, PhD, Scientific Director
Lawrence Liberti, PhD, RPh, RAC, Head, Regulatory Collaborations
Jamie W. Munro, BSc, PhD, Executive Director

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Centre for Innovation in Regulatory Science (CIRS)

Friars House
160 Blackfriars Road
London
SE1 8EZ
UK

Email: cirs@cirsci.org
Website: www.cirsci.org

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