Subscribing to Alerts on the Global Regulatory Intelligence Portal (GRIP)

I. Contents

II. Introduction

The document provides a step-by-step instruction guide on how to sign-up, modify, and delete alert subscriptions on the Global Regulatory Intelligence Portal (GRIP) located at*:*
https://gileadconnect.sharepoint.com/sites/GRIP

Note: all existing users of GRIP 1.0 will be automatically subscribed to receive all GRIP alerts. To modify this subscription, please follow instructions in Section IV., A. Modify Subscriptions. For users new to GRIP (i.e. new employees), please use Section III. Sign-up to Receive Alerts.

III. Sign-up to Receive Alerts

Note: These instructions are intended for users new to GRIP, not previously signed-up to receive alerts in the older version of GRIP.

Open GRIP site in **Chrome or Microsoft Edge** (recommended browsers)
Site URL: https://gileadconnect.sharepoint.com/sites/GRIP

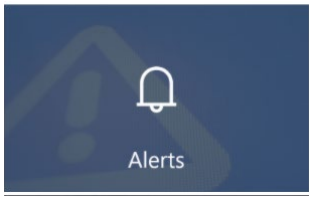
A. All Alerts

1. To automatically subscribe to all alerts, click on the "Subscribe to All Alerts" icon on the GRIP homepage (middle, right of page). You will be subscribed to immediate alerts, frequency can be modified later via the "Edit" function.

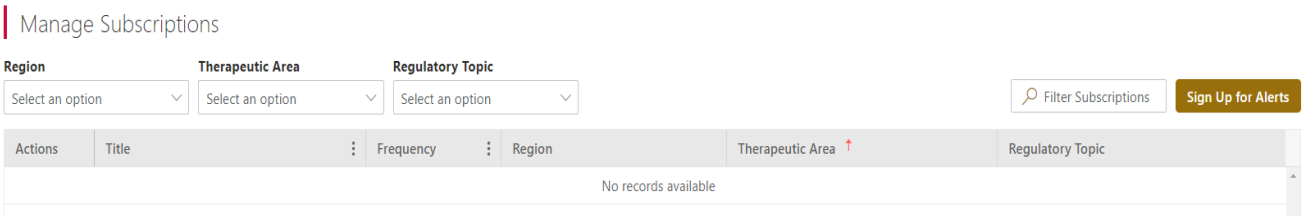
2. You will also receive an e-mail confirming your alert subscription.

B. Customized Alerts (Users NEW to GRIP)

1. To subscribe to customized alerts, click on the "Alerts" icon on the GRIP homepage (top, right of page)

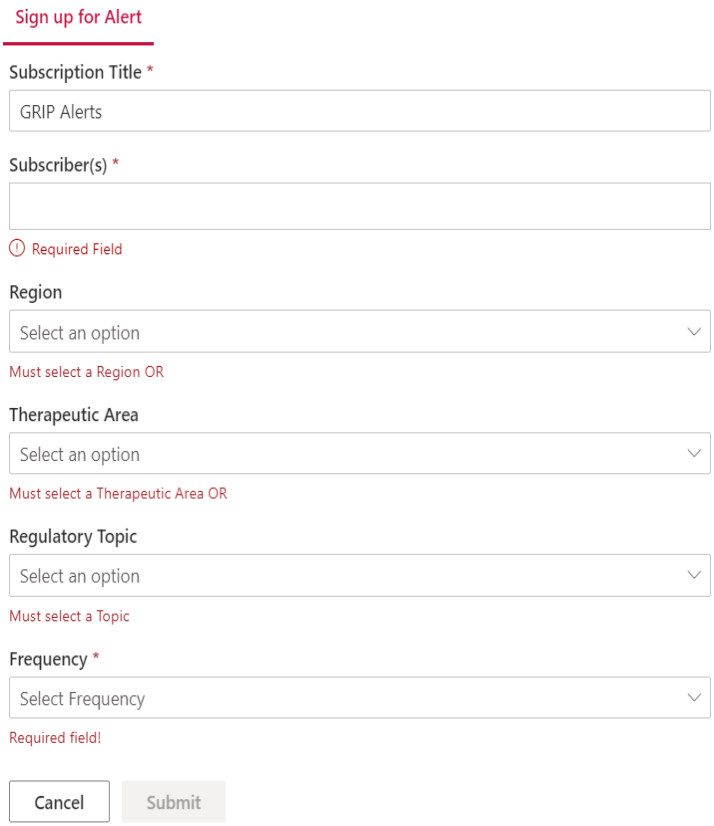


2. The following view will appear:



3. Click the "Sign-Up for Alerts" button located on the top, far right:

4. The alert sign-up form will appear so you can add a subscription title, select the desired fields under Region, Therapeutic Area, and Regulatory Topic, and select the desired frequency for receipt of alerts:



Subscription title: Type a succinct title for the alert type you are choosing to subscribe to. In this example, it is 'GRIP Alerts'.

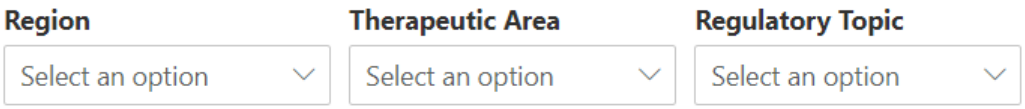
Subscribers: This field is automatically populated with your user ID, however the system will allow you to sign-up other Gilead subscribers on their behalf.

Region, Therapeutic Area, and Regulatory Topic: A combination of single or multiple regions, single or multiple therapeutic areas, and/or single or multiple regulatory topics is allowed. If no selection is made, users will receive alerts from all subsets.

Frequency: Select either immediately, daily, or weekly depending on how often you would like to receive e-mailed alerts, taking into consideration the number of regions, TAs, and topics you are signed-up to receive alerts.

5. Click “Submit”. You will also receive an e-mail confirming your alert subscription

6. Alternatively, using the filters located at the top of the page, select the combination of region(s), therapeutic area(s), and/or topic(s) you are interested in receiving.



7. Click the “Sign-Up for Alerts” button located on the top, far right:

8. Add a subscription title and select alert frequency on the pre—populated form.

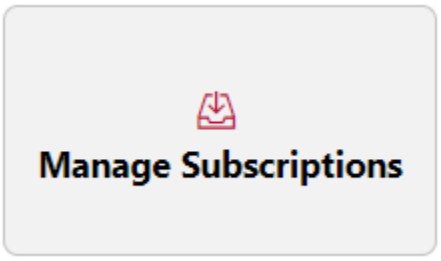
9. Click “Submit”. You will also receive an e-mail confirming your alert subscription

IV. Manage Subscriptions

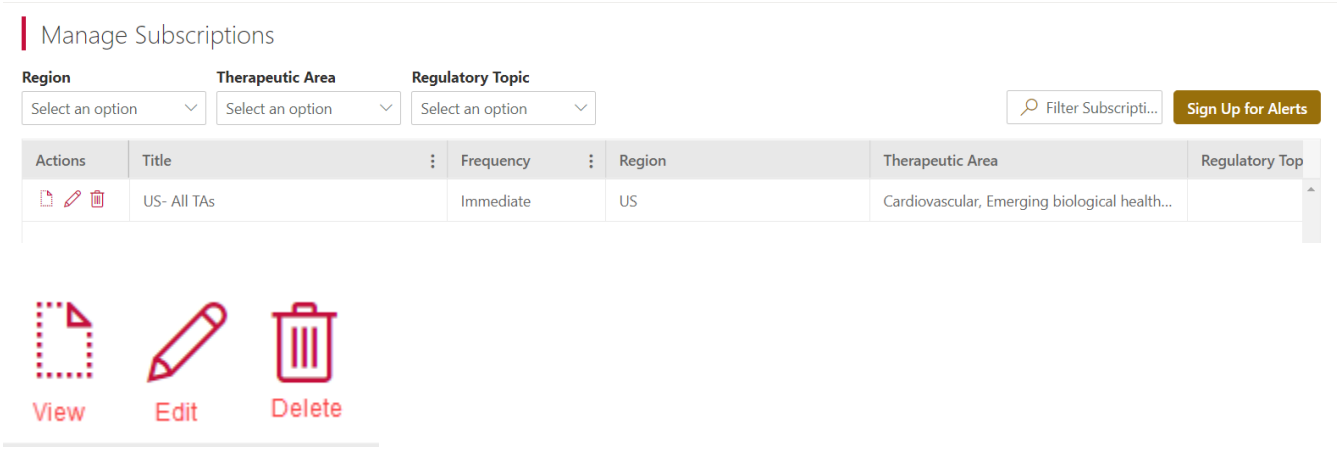
Open GRIP site in **Chrome or Microsoft Edge** (recommended browsers)
Site URL: https://gileadconnect.sharepoint.com/sites/GRIP

A. Modify Subscription

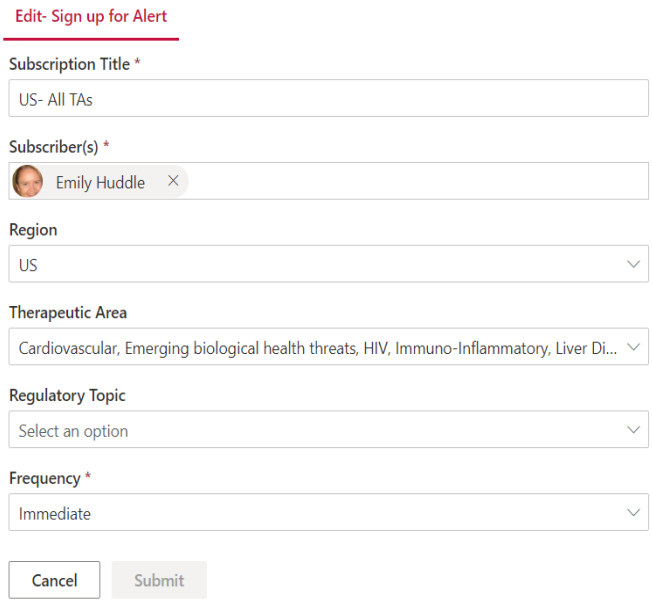
1. To modify any existing alerts click on "Manage Subscriptions" button on the right side of the homepage



2. Select the "pencil" icon next to the subscription you would like to edit.



3. The following auto populated form will appear:



Subscription title: Based on the modifications planned to the existing subscription, you may want to amend the alert title to reflect.

Subscribers: To modify, you may add or remove existing subscribers.

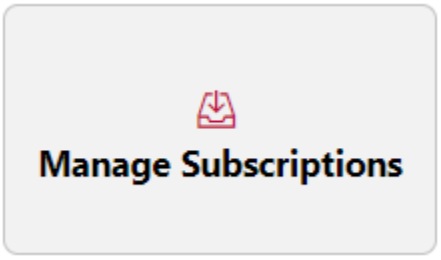
Region, Therapeutic Area, and Regulatory Topic: To modify, you may select or de-select items from these fields.

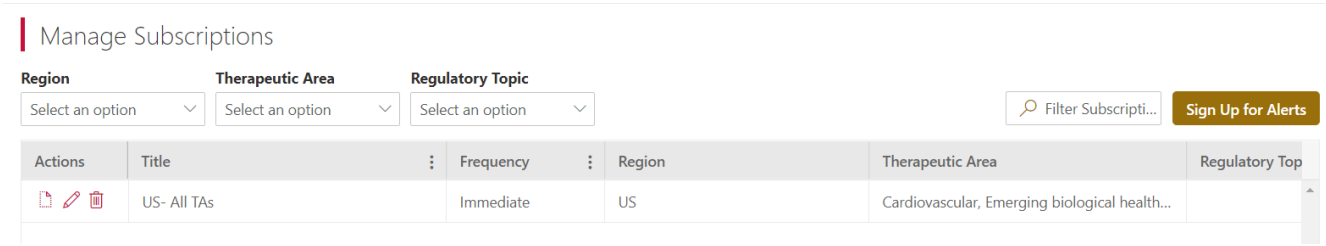
Frequency: To modify, you can adjust to receive alerts at a different frequency (i.e. if you would like to receive less alert notifications from GRIP you can adjust to a daily or weekly frequency).

4. Click “Submit”. You will also receive an e-mail confirming your alert modification.

B. Deleting subscriptions

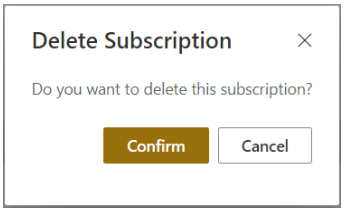
1. To modify any existing alerts click on “Manage Subscriptions” button on the right side of the homepage





2. Select the “delete” icon next to the subscription you would like to edit.

3. Click on “Confirm” button to delete alert permanently.



4. You will also receive an e-mail confirming deletion of your alert subscription.

V. Appendix – Tag Definitions

Region	
Canada	Sign up to alerts for Canada.
China	Sign up to alerts for China.
European Union / EEA	Sign up to alerts for the EU/EEA, excluding Turkey and Ukraine.
UK	Sign up to alerts for the UK.
Switzerland	Sign up to alerts for Switzerland.
Global	Sign up to global alerts.
Japan	Sign up to alerts for Japan.
Africa	Sign up to alerts for Africa.
Middle East	Sign up to alerts for the Middle East, including Turkey.
Russia / CIS / Ukraine	Sign up to alerts for Russia/CIS/Ukraine
Australia / New Zealand	Sign up to alerts for Australia/New Zealand.
Latin America	Sign up to alerts for Latin America.
Asia (exc. China, Japan)	Sign up to alerts for Asia, excluding China and Japan.
US	Sign up to alerts for the US.

Therapeutic Areas	
Cardiovascular	includes pulmonary arterial hypertension (PAH) and other CV diseases of relevance to Gilead
Emerging biological health threats	includes COVID-19, Ebola, Zika virus, and other emerging health threats
HIV	includes HIV (treatment and prep) and associated diseases e.g. cytomegalovirus (CMV) retinitis
Immuno-Inflammatory	includes inflammatory disease including rheumatoid arthiritis, ulcerative colitis and Crohn's disease; as well as the immunological disease GvHD along with any other immuno-inflammatory conditions relevant to Gilead
Liver Disease	includes liver fibrosis, nonalcoholic steatohepatitis (NASH), HBV, and HCV
Oncology	includes myelofibrosis, indolent non-Hodgkins Lymphoma (iNHL), follicular lymphoma, Chronic Lymphocytic Leukemia (CLL), solid tumours, and other relevant oncologic indications that are of relevance to Gilead
Other	includes any other TAs or specific indications that are of interest to Gilead, that do not fit in any of the other TA categories
Respiratory	includes cystic fibrosis and Respiratory Syncytial Virus (RSV)
Viral hepatitis	includes HBV and HCV

Regulatory Topics	
Advanced therapies	Regulatory updates and news pertaining to regenerative therapies including cell therapies, therapeutic tissue engineering products, human cell and tissue products, and genetic therapies.
Advertising and Promotion	Updates and requirements related to Direct-to-consumer (DTC) advertising in the US, as well as Codes of Practices and breaches, and advertising complaints in the EU.
CAR-T	Regulatory updates and news pertaining to Chimeric Antigen Receptor T Cells (CAR-T) therapies
Clinical trials	Updates and requirements pertaining to the conduct of clinical trials, GCP, clinical trial applications, clinical trials legislation, EU voluntary harmonisation procedure, and global simultaneous development in clinical research. Updates and requirements related to expanded access or compassionate use programs, by which manufacturers make investigational new drugs available, under certain circumstances, to treat a patient(s) with a serious disease or condition who cannot participate in a controlled clinical trial. Updates related to WHO approvals and EU Article 58 procedures. Updates and requirements related to biomarkers, biomarker qualification, and pharmacogenetic tests.
CMC/Manufacturing	Updates and requirements pertaining to the manufacturing and quality of medicines and GMP. This also includes any updates on serialisation initiatives and counterfeit medicines.
Data Standards	Updates and requirements related to data standards (e.g. statistical formats, such as IDMP, EU Article 57) and associated terminology.
Generics/Biosimilars	Updates on regulatory environment for generics and biosimilars along with related issues such as IP, data exclusivity, and market exclusivity; as well as for trademarks/invented names.
Labelling/Product Information	Updates and requirements related to labeling in general not related to specific products, such as updates in templates or procedure.
Nonclinical development	Updates and requirements related to *in vitro* and *in vivo* pharmacodynamics (PD), pharmacokinetics (PK), ADME (absorption, distribution, metabolism, and excretion), and toxicology testing (genotoxicity; immunotoxicity; reproductive toxicity)
Pharmacovigilance and risk management	Updates and requirements on pharmacovigilance, benefit-risk assessment and risk management, and adverse event reporting (pre- and post-marketing)
Policy & Legislation	Major pharmaceutical legislation and policy updates
Real World Evidence	Updates, requirements, and examples of RWE and/or RWD: Real-World Data (RWD) are data relating to patient health status

	and/or the delivery of health care routinely collected from a variety of sources. Real-World Evidence (RWE) is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.
Regulatory Authority Announcements	Major announcements and news from key regulatory authorities. Also includes updates and requirements of regulatory procedures relating to interactions with regulatory authorities, including communications, applications, and meetings.
Regulatory Harmonization	Updates and guidances released by ICH; international collaborations; e.g. FDA-EMA confidentiality agreements Key regulatory items on parallel trade
Regulatory milestones and outcomes	Key regulatory and drug development milestones and actions taken on competitor products including refusal-to-file, acceptance of an investigational or marketing application, approvals, non-approvals (e.g. US Complete Response Letters), extension to review periods, faster review designations by agencies, HTA body decisions, safety issues, approvals of variations, and labelling updates.
Regulatory Procedural	Updates and requirements of regulatory procedures relating to interactions with regulatory authorities, including communications, applications, and meetings. This covers regulatory procedural aspects of entire lifecycle of drug development including pre-submission, submission of marketing authorisation, post-authorisation activities including transparency initiatives.
Regulatory submission requirements	Updates and requirements related to regulatory submissions (both paper and electronic, eCTD and non-eCTD)
Special Populations	Updates and requirements on medicines for older people, e.g. special formulations, packaging, and polypharmacy (EU-specific topic) Updates and requirements related to orphan drugs Updates and requirements related to pediatric drug development, exclusivity, and safety (including US BCPA/PREA; pediatric development plans (PDPs, PIPs); PDCO press releases; PDCO membership changes)