



ATAC's Drug Development Committee (DDC) works with government, academia, and the pharmaceutical industry to provide a community perspective into the development of new HIV drugs and the utilization of HIV therapies.

Policies and Procedures

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Appendix: ATAC DDC Membership Form

I. Requirements for DDC Membership

1. ATAC Associate membership status.
2. Completion and submission of the DDC Financial Disclosure Form.
(A membership renewal form will be distributed to the entire DDC membership at least every 2 years. Completing this form is a requirement of all DDC members at the time the form is distributed. Any member who does not fill out and submit the form as requested will be removed from the DDC.)

II. Governance

Two co-chairs share the responsibility of facilitating the DDC. Usually, these positions are for 2-year terms, staggered by 6 months. The DDC co-chairs have special relationships and responsibilities to ATAC staff (the coordinator) and the Steering Committee (SC). The co-chairs are responsible for facilitating monthly DDC conference calls (including gathering agenda items and posting a final agenda before the call), helping organize DDC meetings, coordinating DDC activities and communications, conducting votes of the DDC members, etc.

Areas of responsibility in the DDC currently include several key areas of work, which can be covered by individuals or (as needed) by committees. The work areas are described below:

- *DDC Liaisons* (see job description, Section V).
- *Membership Tracking*—ensuring new members are welcomed and “plugged in” to the current DDC process.
- *Recruitment and Outreach*—working with the ATAC membership committee, seeking new members for DDC.
- *Editorial*—editing and reviewing all letters and publicity/announcements sent out that represent DDC positions.
- *Website*—maintaining the DDC area of the ATAC website, including company information, various member resources, publicity/announcements, etc.

III. Voting & Sign-ons

For all issues that must be settled or finalized by vote, the DDC operates by

- “Consensus minus 1” for all those present at meeting held in-person or conference call [“Consensus minus one” is a way to make decisions and conduct DDC business. This means that when a proposal or idea is being put forth to the group, members have the option to consent (no action or statement required), “stand aside” (in the event of a conflict of interest or a need to express abstention or dissent--just not in a way that stops the motion), or “block” (a position designed to specifically to stop a motion from passing). One block is not sufficient to stop a motion (thus “consensus minus one”), but two or more blocks will stop a motion from being passed by the group.]
- A 2/3 (two-thirds) majority of the votes cast for votes conducted via the DDC e-mail list

All votes must be coordinated and put forth by the Co-chairs. Issues can be brought forward to vote by DDC members to the Co-chairs. Co-chairs will gather and organize any needed information and call the question to the group either by e-mail or by conference call. Enough time should be available to allow for the issue to be presented to the group, for a vote to be held, and for the necessary action(s) to be taken, otherwise the issue might have to be dealt with outside of or without the participation of the DDC.

Sign-on procedure: For non-DDC-generated letters that need sign-on in less than 3 days, 3 DDC members are authorized to sign-on for the DDC. The DDC membership decides by vote who these persons will be and votes on new persons as necessary (usually if someone steps down or can no longer be a “sign-on” person). For letters that have more than 3 days reply time or for structural/process changes, 2/3 of the people voting on the e-mail question, or consensus-1 on the in-person vote, are required as listed above.

IV. Representation on the ATAC Steering Committee

As described in ATAC’s Bylaws, the DDC is automatically entitled to representation on the ATAC Steering Committee (SC). The DDC membership will elect one SC Representative each year when the previous term has expired. The SC Representative must be a DDC member and can be elected to this position for multiple terms. The SC representative can be a DDC co-chair, but this is not required. The SC Representative will be chosen by vote of the DDC membership. An *ad hoc* nominations process for SC Representative can be initiated before the current term expires to ensure a smooth transition to the SC.

The SC Representative will be expected to perform all the duties of SC members as described in the ATAC Bylaws. The DDC’s SC Representative will give regular updates to the SC about DDC activities, requests, etc. Likewise, the SC Representative will report monthly to the DDC membership via written e-mail posts on the DDC list, on the DDC conferences, or at in-person DDC meetings.

V. DDC Liaisons

As part of its organizational structure, the DDC has among its members **liaisons** to pharmaceutical companies, government agencies (mainly FDA), and other entities as appropriate with the ATAC mission of advancing research on HIV/AIDS. One or both of the DDC Co-chairs must ensure the liaisons fulfill their responsibilities. (Alternatively, a Liaison Coordinator may be assigned to work with liaisons).

Liaisons have special responsibilities to monitor and keep current with issues concerning their assigned companies or agencies and to report and share such information with the DDC membership (as described below).

1. The DDC will have at least 2 (and preferably no more than 3) liaisons for each major drug company or entity (such as FDA). The pairing of more experienced activists with less experienced activists is encouraged. The more experienced (primary) liaison must participate on DDC monthly calls whenever possible. Newer (secondary) liaisons should also participate but may substitute for primary liaisons on monthly calls, etc.
2. DDC liaisons are the official DDC contact/point people between the DDC and their assigned company or other entity. While any DDC member may have contact with any company or other entity, this should be done as an individual and not as a DDC representative. For DDC-related affairs and follow-up, the DDC liaison must be the primary contact for DDC business with the assigned company.
3. Information received by other DDC members regarding the assigned company should be forwarded to the liaison team as soon as possible. This includes copying liaisons on any communication between other DDC members and the assigned company. The purpose of this provision is to avoid confusion and create clear lines of communication as well as responsibility.

Duties and Responsibilities of DDC Liaisons:

1. Ensure monitoring duties are covered among members of the liaison team. If all liaisons are unavailable at the same time, they will contact the DDC Liaison Coordinator for assistance. The purpose of this provision is to avoid confusion and create clear lines of communication as well as responsibility.
2. Participate in and prepare short updates for DDC monthly calls. If unable to participate on the call, the liaisons should send an update to the list in advance of the call (even when there is not much to report). The reason for having at least 2 liaisons is for coverage, so at least one should be present on calls and responsible for providing updates to the group.
3. Maintain monthly contact with assigned drug company or other entity. This contact can range from a quick check-in e-mail message to a formal letter or conference call, depending on the drugs being developed at the time or immediacy of a particular issue. The purpose of this monthly contact is to maintain a proactive stance and to keep the DDC apprised of important events occurring within each company so that timely decisions can be made and emergency reactive decisions can be averted.
4. Monthly reporting of any important information via DDC calls or meetings. Urgent information should be transmitted immediately to the DDC list via e-mail. Reports can be submitted by e-mail to the DDC list in writing as well as orally on the conference calls.
5. Supply the ATAC Coordinator with company contact information, including:
 - a. contact names
 - b. addresses
 - c. phone numbers
 - d. e-mail addresses

This information should be sent to whomever is responsible for the DDC website (Co-chair, SC representative, DDC member, etc.) as part of regular website updates (as well as information about currently marketed products to treat HIV or related conditions, pipeline agents and what phase of development they are in, etc.)

6. Coordinate and facilitate telephone meetings between the DDC and the assigned drug company as needed. This includes:
 - a. Prepare timely agendas and a short list of questions/issues for call after requesting input from the DDC on any important issues.
 - b. Chair conference calls with assigned company or entity.
 - c. Prepare written minutes of conference calls and forward to the ATAC Coordinator and DDC no later than 1 week after the call.
7. Coordinate and facilitate in-person meetings between the DDC and the assigned drug company as needed. This includes the following tasks:
 - a. Propose meeting to the assigned company or entity, establish a date and time, inform them of the ATAC meeting fee of \$15,000 (if a drug company), and refer them to the ATAC coordinator to follow-up on these arrangements.
 - b. Prepare agenda and list of questions/issues to be forwarded to the ATAC Coordinator and DDC no less than 2 weeks before date of the meeting.
 - c. Chair/moderate the meeting.
 - d. Ensure that notes are taken (assign note-takers). Session notes must be forwarded to the ATAC Coordinator and DDC no later than 1 week after the last day of the meeting, unless otherwise agreed upon by the DDC.
 - e. Compose the meeting follow-up letter that includes information from the meetings, as well as demands and requests agreed upon at the meeting and forward the letter to the

DDC via the e-mail list for comment within 1 week of the meeting. The letter must be sent to the company or entity within 2 weeks of the meeting.

VI. Meetings

Conference calls

Regular conference calls (1.5 hours) are held on the ATAC conference call line generally once per month (for example on the second Thursday at 4pm Eastern time). The week before a conference call, the DDC Co-chair(s) will send out a call for agenda items and a reminder for the call. Liaisons will be responsible for preparing short oral or written updates to submit before the call. A final agenda will be sent out by the Co-chair(s) in advance of the call. The DDC Co-chair(s) will facilitate the call, including assigning a note-taker (who will send draft notes to the Co-chairs for distribution to the group within 1 week of the call).

DDC meetings

DDC meetings are planned 3 to 4 times each year. The DDC Co-chairs take the leadership initiative in organizing such meetings, consulting with ATAC staff according to established procedures. For any particular meeting, the relevant DDC liaisons (to the companies or groups to be met with) will be responsible for the duties outlined in section V (part 7) above. In order to be most effective and economical, DDC meetings should not include more than 20 to 25 DDC members. While new DDC members are encouraged to attend, there must be a "critical mass" of more experienced activists in attendance to ensure a high-quality dialogue with the groups being met with (also serving to mentor the newer attendees). For meetings where the number of DDC members who respond exceeds the number of available slots, consideration and priority might be given to the following:

1. That DDC leadership (co-chairs) attend
2. That the relevant DDC liaisons attend
3. That participation in at least the last 2 DDC conference calls be considered a prerequisite for meeting attendance
4. That overall participation in the DDC (posting information and responses on the DrugDev list, participating on DDC conference calls, regularly reporting on assigned groups as DDC liaisons, taking notes for conference calls, etc.) be considered by the DDC Co-chairs when and if the need to restrict attendance becomes necessary.

A typical DDC meeting should include the following elements and considerations:

- At least 1 hour should be devoted to a pre-meeting regarding issues to cover with each company. The pre-meeting will be led by the company liaison(s).
- If confidentiality agreements are required to be signed, the liaison(s) will distribute these to the group and collect the signed forms to give to the company at the meeting.
- The liaison(s) should assign a notetaker for the meeting. Meeting notes should be sent to the company liaison(s) and DDC Co-chairs within 1 week of the meeting. Draft minutes may need to be run by the company before distribution to the DDC (to avoid breach of confidentiality).
- A post-meeting should be held to recap what was discussed with each company and what information will be included in the follow-up letter (see section V).
- Each company meeting will be opened by a DDC Co-chair who will give a short overview of the DDC and ATAC, and will lead introductions. The meeting is then turned over to the DDC liaison(s) for facilitation (taking a queue for questions, monitoring the time, moving the agenda along, etc.)
- Company representatives should be seated together (not interspersed among DDC members), with a few seats toward the head of the table as space allows. Additional seats can be arranged along the wall if there are more than just 3 or 4 company officials attending.

- General tips for DDC meetings with companies or other groups:
 - Questions can be asked by raising hands and following the queue kept by the liaison/facilitator. Participants should be aware of the number of questions they ask, and whether or not they are asking too many questions. Also, try not to ask repeat questions that have already been asked or covered; it's OK to "pass" when called on if there is nothing new to contribute.
 - DDC members should not argue or openly disagree with each other during meetings with companies.
 - Clapping at the end of company meetings is inappropriate.
 - New DDC members (or those attending a DDC meeting for the first time) should be "paired" with an experienced member to sit with at the meetings. The experienced person can act as a resource during the meeting (to pass notes to, ask questions of, etc.) DDC Co-chairs will assign new members with their "meeting mentors."

Non-DDC meetings

In situations where DDC members attend non-DDC-organized meetings or focus groups with drug companies, government entities, or other organizations, these individuals should:

- inform the DDC membership of attendance.
- submit a written or oral summary report of meeting proceedings, if relevant to the interests of the DDC, unless prohibited by a signed confidentiality agreement. All drug company meetings are presumed to be relevant to DDC interests. The purpose of this provision is to promote information-sharing among members.

VII. Media and publicity relations

DDC press releases, statements to the media, letters, etc. cannot be issued at random. Press releases that mention or quote the DDC (or any of its members as DDC representatives) *must be approved* by a vote or consensus of the DDC (as presented via the Co-chairs). If approved by the DDC, letters and press releases should be reviewed by the co-chairs and editorial subcommittee members (as needed) before final issue.

Any requests from outside media for interviews or statements should be directed to the DDC co-chairs. Any DDC statements, letters, press releases, etc. relate to the DDC alone and do not represent the views or opinion of ATAC as a whole unless the ATAC Steering Committee or membership has also approved such statements.

Unauthorized representation of the DDC by a DDC member will result in the possible removal of that member from the DDC (as per section VIII below).

VIII. Removal of a member

Removal of members is the responsibility of the DDC Co-chairs. Removal of any member from the DDC can be appealed to the ATAC Steering Committee as per the ATAC Bylaws. Removal of a member from the DDC may be necessary under certain circumstances:

1. Any DDC member who voluntarily resigns from the group (this includes not submitting an membership renewal form) will be removed from the DDC e-mail list and from access to members-only communications immediately. This person will have to re-apply for membership if he/she wants to rejoin the group.
2. Any DDC member who violates the DDC's statement of confidentiality or the e-mail lists rules, or who is found to have provided false information on a DDC application or membership renewal form, will be immediately removed from the DDC as well.

3. Any DDC member who is no longer an Associate member of ATAC will also be removed from DDC. This applies to individuals who contract with or go to work for pharmaceutical/biotechnology companies involved in HIV research, communication groups who contract with or work for such companies etc.

In less certain situations, for example where a member is being disruptive to the group or potentially damaging its credibility through inappropriate representation/communication (see section VII above), the Co-chairs may confer with the DDC membership to vote on whether or not to remove that particular member from DDC.

IX. Other issues

ECAB Meetings

A standing agreement exists between the DDC and the European Community Advisory Board (ECAB), its European counterpart. Several times a year, as budgets permit, each group sends a representative to the other group's meetings. This enables each group to gauge the accuracy of information being told to the other by pharmaceutical companies, as well as to communicate in person various issues faced by the other group.

Per this agreement, the host group is responsible for the visitor's meals and accommodation, while the visitor's group is responsible for travel expenses. In general, the DDC aims to send representatives to ECAB meetings (typically held in Brussels) 2 to 4 times each year and should budget accordingly. (However, ECAB meets with companies more often each year than DDC). Selecting which meetings the DDC attends and bringing forth the request for representation is the responsibility of the Co-Chairs. Selection is made by the group via vote or consensus. (DDC Co-chairs are eligible to represent the DDC at ECAB meetings as well.)

Selected representatives are responsible for providing a written summary of the meeting to the DDC within 2 weeks of returning from the meeting.

Currently, there is no formal internal DDC process for selecting its representatives to these meetings. DDC members who are subscribed to the ECAB list, or ECAB members subscribed to the DDC list, will usually inform the group of ECAB meeting opportunities ahead of time via the DDC list. The following issues are presently taken into consideration by the DDC when selecting or voting on whether to send a representative to an ECAB meeting and who that representative should be:

- The current issues and priorities associated with the companies on the meeting agenda;
- The experience/expertise of a DDC member with issues being covered at the meeting;
- The availability of a specific DDC company liaison to attend a meeting with the relevant company;
- Proximity to Europe of any DDC members during the time of the meeting (with the idea that savings can be realized for the DDC if transportation costs are reduced by a person being nearby the ECAB meeting);
- The number of times a DDC member has represented the group at ECAB meetings (with the idea that new people should be given opportunities to do so as well)

Community reception

Each year, the DDC hosts a community reception, usually in conjunction with the annual Conference on Retroviruses and Opportunistic Infections or CROI (www.retroconference.org). The co-chairs or designated DDC members should contact the CROI Secretariat to register the social event before the conference (usually in late January or February). It is important to find out when various other dinners or programs are scheduled so that the DDC reception conflicts with as few other events as possible. A flyer should be made several weeks before the reception to announce on ATAC, ECAB, and other e-mail lists and to post at CROI with the appropriate information (location, date, time, directions, etc.)

All community members (US and international) are invited to this reception, which usually includes light food and beverages (based on budget limitations set during the DDC budget planning process each year). This is a perfect opportunity to network, recruit new DDC members, education people about DDC, etc. Employees of pharmaceutical companies, marketing/communication companies, and other commercial groups involved in HIV/AIDS should not attend as this is truly a community reception.

ATAC DrugDev e-mail list

All DDC members agree to the following statements as a condition of joining the group and participating on its e-mail list, "ATAC DrugDev" —

- 1- I will refrain from engaging in personal attacks on others--even if I strongly disagree with their views.
- 2- I will respect the confidentiality of others.
- 3- I have read the mission of the list and I will post messages only on issues that are pertinent to the list
- 4- I will respect people's gender, ethnicity, sexual orientation, religion, HIV status, political affiliations, etc.
- 5- I will not spam the list with for profit information
- 6- I believe HIV is the cause of AIDS

I understand that if I do not comply with these requirements I may be expelled from this list by the administrator



ATAC DDC Membership Form

Section I. Member information and Confidentiality Agreement.

1. Name: _____
2. Street Address: _____
3. City, State, ZIP: _____
4. Telephone: (Area code and number): _____
5. E-mail address (for ATAC DDC correspondence): _____

6. Do you work (paid or volunteer) for any HIV-related organization? (Check one) Yes or No

6a. If you answered "Yes" above, then what is the name of the organization, and what is your title? (You can list more than one affiliation.)

7. Confidentiality Agreement: Do you agree to abide by the following statement? (Check one; answering "No" will automatically disqualify you from membership in the ATAC DDC)

I agree to hold in confidence any information shared on the ATAC DDC website or e-mail list ("ATAC DrugDev") that is not already in the public domain (eg, conference presentations, published literature, Internet content, etc.) I also agree not to share any information from internal ATAC DDC discussions (whether in-person, on conference calls, or via e-mail) with other persons who are not other ATAC DDC members, unless authorized to do so by ATAC DDC leadership or as the result of a group consensus or vote (eg, as part of a directed group action or work plan). Finally, I will not disclose personal information that may be shared through the ATAC DDC, such as HIV status or other health conditions, without express permission of the affected individual. I understand that violations of confidentiality as described herein will result in the termination of my DDC membership.

Yes or No

8. Optional Info: *You do not have to answer questions 8a–8d.*

8a. What is your sex?

8b. What is your ethnicity/race?

8c. Are you living with HIV?

8d. Do you have any skills or areas of interest that you would like to apply to your work as a member of the ATAC DDC? If so, what?

Section II. Financial Disclosure Form

All DDC members are required to complete a Financial Disclosure Form regularly (at least once every 2 years, as instructed by the DDC co-chairs). Any changes that may occur in circumstances occur before a new Financial Disclosure Form is required, shall require the submission of an updated Financial Disclosure Form within 30 days of that change. All DDC guests are required to complete this form before attending a DDC meeting.

Financial Disclosure Forms of DDC members will be kept on file at ATAC Headquarters. These Disclosure Forms will be available to any DDC member upon a written request to the DDC Co-chairs; members will be notified if a request has been made to view their financial disclosure forms and by whom. Any DDC member who discloses the contents of another member's disclosure information to a non-DDC member is subject to removal from the DDC.

1. Please list your any fundraising responsibilities you have at your current employer. (If not applicable, please so indicate). _____

2. Please list the names of all pharmaceutical companies from which you received individual consultant fees and/or honorarium which you did not contribute to a non-profit organization in the last year, also include the percentage of your annual income represented by pharma income. Please note that listing the actual amounts received is optional. _____

3. If you are an Executive Director, member of the development staff, grant writer, or member of any financial committee of the Board of Directors of an AIDS service organization (ASO), please list the names of all pharmaceutical company ("pharma") contributors and the annual percentage of such contributions received by your organization in relation to your annual budget for the past 3 years. Please note that listing the amount of individual grants from individual pharmaceutical company contributors is optional.

4. HIV research, treatment, or HIV-related use pharma, diagnostic, or biotech equitable ownership (stock, etc.) by an individual or their spouse (not including mutual funds or stocks strategically held to affect stockholder meetings, etc.) makes an individual ineligible for DDC membership. If you own such stock in a company *not involved* in HIV, you or your spouse are required to divest yourself of such ownership within 30 days of the company entering into the HIV or HIV-related use arena. If you or your spouse own stock etc. for strategic purposes, you are required to submit proof of the strategic nature of that ownership. Do you or your spouse/significant other own stock or other equitable interest in any HIV or HIV-related use pharmaceutical, diagnostic, or biotech company?
 Yes or No
5. Please list all government, industry, and ASO Boards on which you currently serve or have served in the last 3 years. _____

6. Please list other income or facts related to financial conflicts of interest that you think should be made known to the DDC, including matters related to members of your household or your significant other. _____

Do you declare that the information you have provided is true to the best of your knowledge? Yes or No

Type your name (to be counted as your signature): _____