

QUANTIFICATION OF ENDOGENOUS STEROIDS FOR THE PURPOSE OF LONGITUDINAL PROFILING IN BLOOD WORKING GROUP

Terms of Reference

The WADA "Quantification of Endogenous Steroids for the Purpose of Longitudinal Profiling in Blood" Working Group (Steroids in Blood WG) is a specific Working Group created by WADA Management at the request of the WADA Laboratory Expert Group and the WADA Athlete Biological Passport Expert Ad Hoc groups.

These Terms of Reference are approved by the WADA Director General, following consultation with the responsible Director in charge of the Group and the Chair of the WADA Health, Medical and Research Committee.

Purpose

In March 2019, the Court of Arbitration for Sport (CAS) confirmed the two first use cases based on longitudinal serum testosterone profiling. Following this decision, the WADA Laboratory Expert Group and the WADA Athlete Biological Passport Expert Ad Hoc groups suggested the formation of a specific Ad Hoc working group to formalize the pre-analytical and analytical requirements of this approach in the form of a WADA Technical Document.

It is expected that the Working Group will deliver to the WADA Health Medical and Research (HMR) Committee (1) a report at the end of 2020 that includes progress on activities, outputs and recommendations for implementation, (2) a final report and (3) a new technical document or guidelines including all the requirements for ADOs and laboratories to perform the measurement of endogenous steroids in blood.

It is forecast that the Steroids in Blood WG) will complete its mandate within a 12-18 month period (i.e. from May 2020 to November 2021). It will deliver recommendations to WADA during this period. The necessary meeting timelines will be framed with this in mind.

Steroids in Blood WG ToR: Updated December 2020

¹ WGs are created on an as-needed basis only, and generally with a defined mandate requiring deliverables within a set timeframe. Where the expected deliverables are not met, an extension of mandate is possible, however it is not expected that WGs continue indefinitely. If it is considered that their work should be ongoing in nature, whether WG should be elevated to an Expert Advisory Group would need to be determined.

Objectives/Key Activities

- 1. Review the literature related to steroids quantification in blood;
- 2. Review analytical methods and approaches to define a suitable and cost-efficient method to quantify endogenous Steroids in Blood;
- Assess the feasibility of developing an additional module of the Athlete Biological Passport (ABP), using a similar statistical approach to allow the longitudinal follow-up of endogenous steroids levels in blood;
- 4. Suggest adaptation of existing International Standards and/or Technical Documents, or develop new regulation (i.e. new Technical Document or Guidelines) if needed for the quantification of endogenous Steroids in Blood and
- 5. Advise WADA on the implementation phase of this tool to ensure reliable use among antidoping partners.

Reporting Structure

The Steroids in Blood WG reports to WADA Management and through its Chairperson, reports to the WADA Health Medical and Research Committee.

Membership/Composition

The composition of the Steroids in Blood WG shall not exceed a maximum of 8-10 members however an exception may be applied if deemed necessary.

The WADA Director General, following consultation with the responsible Director in charge of Steroids in Blood WG, will appoint members to the Steroids in Blood WG.

Members are selected on the basis of their relevant background and experience (e.g. expertise in the areas of analytical chemistry, steroids analysis, endocrinology or ABP).

The Members of the Steroids in Blood WG are as follows:

- 1. Dr. Tiia Kuuranne
- 2. Dr. Jenny Schulze
- 3. Dr. Arieh Cohen
- 4. Dr. Günter Gmeiner
- 5. Prof. Eberhard Nieschlag
- 6. Prof. Martial Saugy
- 7. Dr. Reid Aikin
- 8. Dr. Norbert Baume (Chair)

If required, additional experts may be called upon on an ad-hoc basis for their contributions.

Member terms reflect the mandate of Steroids in Blood WG, i.e. until November 2021. If the work of a Steroids in Blood WG is not completed within the originally planned timeframe, and is extended, the composition and terms of members are reviewed to ensure their relevance remains.

Chair/Rapporteur

The Steroids in Blood WG Chair² is selected based on his/her proven record and expertise in analytical chemistry, steroids analysis, endocrinology or ABP.

He/she shall act as the official reporter who is responsible for ensuring appropriate coordination with WADA Management and for providing accurate and timely information on all relevant issues.

WADA Liaison

The WADA Science & Medical Department, and in particular the ABP Manager, will serve as the primary liaison between WADA and the Steroids in Blood WG.

Additional WADA Science & Medical staff may also participate in Steroids in Blood WG meetings as WADA experts on particular subject matters and to provide general support to the group where required.

Meetings and Working Norms

The Steroids in Blood WG will meet in person, or virtually via video or teleconference (as determined by WADA) as many times as is necessary to complete its mandate.

The Steroids in Blood WG normally operates on the basis of consensus and maintains as informal a manner as is possible or appropriate for the conduct of business. Consensus will be sought whenever possible. In the event of divergence of opinion or disagreement concerning recommendations, the absolute majority (determined by vote by hand) will rule. In the event of a tie, the Chair has the casting vote. There is presently no formal practice concerning a quorum. The Chair has the responsibility to determine if a quorum is present. Meeting notes will record any dissenting opinion on request.

The Chair may limit discussion of resurfacing issues by referring to previous recommendations or conclusions of previous discussions.

Meeting notes of the Steroids in Blood WG meetings, reports and correspondence relative to the group's work shall be open, recorded and retained at the WADA Headquarters.

Conflict of Interest

Steroids in Blood WG members will be bound by the Conflict of Interest policy adopted by the WADA Foundation Board in November 2019³, and will be required to annually complete and sign a Statement of Absence of Conflict of Interest in accordance with the policy.

² There are occasions where WADA staff may chair a WG, e.g. when an external chair is not deemed to be practical.

³ WADA's Foundation Board approved a set of governance reforms in November 2018 at its meeting in Baku, Azerbaijan. In 2019, WADA's Statutes were modified to reflect these reforms, and a new set of bylaws and operational regulations were created to supplement the formal Statutes. They were approved by WADA's Foundation Board in November 2019 in Katowice, Poland.

Confidentiality

All group members are required to sign a Confidentiality Agreement upon appointment (and again at the start of each year if their appointment is renewed). This ensures all members reflect on the confidential nature of their WADA work and confirm their adherence to such confidentiality rules. Signing this document each year is a new process as of 2020 (as a result of the governance changes mentioned above); previously members were only required to sign once.

Communications and Media

All Steroids in Blood WG members must read and comply with WADA's Media Relations policy. If a member should receive a request for an interview in relation to their role in WADA or WADA's work they should first consult with the WADA Media Relations Senior Manager or (if absent), with the WADA Communications Director.

Budget and Financial Support

WADA has budgeted for the Steroids in Blood WG for up to 18 months. Should an extension of the mandate be required, additional budget will need to be approved prior to final confirmation of the group continuing.

WADA shall provide the necessary administrative and operational resources for meetings. WADA will meet all travel and accommodation costs, as well as most meals onsite. A daily indemnity is provided to cover incidental costs during travel to and from the meeting.

Where meetings are held virtually and meet certain rules such as a minimum duration, a daily indemnity for virtual attendance is disbursed.

It is acknowledged that some experts go above and beyond, including providing extensive advice throughout the year, outside of annual meetings. WADA offers a further daily indemnity to experts for such work carried out. The specific indemnity details are outlined in the full "Overview of WADA Working Groups" document provided to Members on appointment.

Effective Date

These ToR originally came into effect on 13 May 2020. The mandate remains the same as initially drafted and/or approved. The ToR have however been updated to reflect practical changes to the way in which WADA manages its Working Groups which were approved in November 2020 and come into effect on 1 January 2021.

These ToR are published on the WADA website.