



WORKING GROUP FOR THE IMPLEMENTATION OF GH BIOMARKER ANALYSIS FOR THE ABP

Terms of Reference

The WADA Working Group for the Implementation of GH Biomarker Analysis for the ABP (Endocrine Analytics WG) is a specific Working Group¹ created by WADA Management at the request of the previous Ad-Hoc WADA Endocrine Module Working Group.

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

Based on the recommendations from previous working groups for the development of the “Endocrine Module” of the Athlete Biological Passport (ABP), recent inter-laboratory comparability studies and validation of an ABP approach for the detection of Growth Hormone (GH) use with the longitudinal application of the biomarkers test have been successfully carried out. In order to proceed towards implementation for routine application, this Working Group (WG) will oversee the harmonization of analytical approaches for the Endocrine Module of the ABP.

It is expected that the WG will deliver to WADA 1) recommendations for applicable Guidelines for laboratories to perform measurement of GH biomarkers in blood for the ABP, and 2) recommendations for implementation of an applicable laboratory quality control program.

The WG may be called upon for further work after the delivery of its report; however, this is subject to the findings of their research and analysis and any extension will be subject to the approval of the WADA Director General.

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

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 analytical strategies to define suitable, harmonized and cost-efficient methods to quantify the GH biomarkers IGF-1 and P-III-NP for the purposes of the ABP;
- 2) Define specific requirements for suitable internal and external quality controls for such an approach;
- 3) Provide recommendations for adaptation of existing International Standards and/or Technical Documents, or develop new regulation (i.e. new Technical Document or Laboratory Guidelines) if needed for the quantification of GH biomarkers for the ABP; and
- 4) Advise WADA on the implementation phase of this tool to ensure reliable use among anti-doping partners.

Reporting Structure

The Endocrine Analytics WG reports to WADA Management and through its Chairperson, reports to the Health, Medical and Research Committee.

Membership/Composition

The composition of the Endocrine Analytics WG for the ABP 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 the Endocrine Analytics WG, and the Chair of the WADA Health, Medical and Research Committee, will appoint members to the Endocrine Analytics WG.

Members are selected on the basis of their relevant background and experience (e.g. expertise in the area of GH Biomarkers analysis).

The Members of the Endocrine Analytics WG are as follows:

1. Prof. Mario Thevis
2. Prof. David Cowan
3. Dr. Daniel Eichner
4. Dr. Reid Aikin (*Chair*)
5. Dr. Norbert Baume
6. Dr. Osquel Barroso

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

Member terms reflect the mandate of Endocrine Analytics WG, i.e. until November 2021. If the work of the Endocrine Analytics 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 Endocrine Analytics WG Chair² is selected based on his/her proven record and expertise in analytical considerations for the 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 and Medical Department, and in particular the Deputy Director, Athlete Biological Passport, will serve as the primary liaison between WADA and the Endocrine Analytics WG.

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

Meetings and Working Norms

The Endocrine Analytics 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 Endocrine Analytics 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 Endocrine Analytics WG, reports and correspondence relative to the group's work shall be open to Members, recorded and retained at the WADA Headquarters.

Conflict of Interest

Endocrine Analytics 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 Endocrine Analytics 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 Endocrine Analytics WG for up to 12 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 19 November 2020. The mandate remains the same as initially drafted and/or approved. The ToR have however been adjusted to reflect practical changes to the way in which WADA manages all of its Working Groups and which come into effect on 1 January 2021.

These ToR are published on the WADA website.