

FREQUENTLY ASKED QUESTIONS (FAQs) ON THE Technical Document on Athlete Passport Management Unit (APMU) Requirements and Procedures (TD2019APMU)¹

1. What is the goal of the TDAPMU?

The TDAPMU aims to harmonize effective Passport management by APMUs. This is achieved by further defining the roles and responsibilities of the APMU in a Level 2 (mandatory) document, providing requirements for the structure of APMUs, outlining an APMU approval process, and defining specific procedures for Passport management by APMUs.

2. Why is harmonization of APMU activities important to anti-doping?

Recognizing the growth in *ABP* programs worldwide, the APMU role has been confirmed as a fundamental component of global anti-doping activities. Passport information, via the APMU, can be used to drive essential anti-doping activities including *Testing*, analysis, *Sample* storage, and investigations. When assessing the current APMU system, many of the challenges arise in internal APMUs associated with *ADOs*, where there is considerable variability in the performance of, and resources dedicated to, internal *ABP* management. Depending on the case, these challenges include non-compliance with applicable standards for Passport management (e.g., unsatisfactory review of *Atypical Passport Findings* by Experts and lack of entry of APMU Reports into *ADAMS*), inadequate experience with Passport review due to low volume of Passports, limited qualifications and expertise, a lack of reactivity, interference with the independence of the APMU system, and/or demonstrated corruption. The current TDAPMU aims to address these challenges in order to raise the effectiveness of Passport management globally.

3. What is the role of an APMU?

An APMU is responsible for the management of Passports according to Annex L of the ISTI, providing *Target Testing* recommendations based on Passport data, determining sample validity, and providing support as required to the *ADO* in charge of result management for the *ABP* (Passport Custodian) in defining priorities in order to optimize the efficiency of their *ABP* program.

¹ The FAQs on the TD2019APMU is a supporting document to assist Laboratories and *ADOs* with the implementation of the TD2019APMU. Where the interpretation of any text within the FAQ is in contradiction with the TD2019APMU, the TD2019APMU shall prevail.

The APMU role is distinct from the role of a testing manager within an *ADO* who integrates multiple sources of information in order to drive testing. A testing manager will integrate information from multiple sources, including from their APMU, the *Athlete's* competition schedule, specific intelligence information on *Athletes*, and whereabouts information, in order to direct testing.

An important distinction between Passport management, as it pertains to Annex L of the ISTI and to TD2019APMU, and test planning is that potential for bias in Passport management may be reduced by concealing the *Athlete's* identity, whereas test planning is specifically improved by knowledge of *Athlete*-specific information.

4. Why are APMUs being centered around *WADA*-accredited Laboratories?

WADA-accredited Laboratories have the highest concentration of scientific expertise in anti-doping, and continue to be on the cutting edge in terms of recent developments in anti-doping science as they are involved in a significant amount of anti-doping research. Thus, while highly skilled individuals certainly exist outside of laboratories, the long-term stability of expertise specific to the *ABP* will always, because of their very nature, exist in the Laboratories.

With respect to the steroidal module, most of the steroid *ABP* Experts are found within *WADA*-accredited Laboratories. Indeed, a large proportion of steroid profiling research is carried out within *WADA*-accredited Laboratories. Because of this steroid expertise, and their independence from the Passport Custodian, Laboratory-associated APMUs can act as the first Expert reviewing an atypical steroidal Passport (see L.2 of Annex L of the ISTI), without the need to send the Passport to an external Expert – resulting in a more rapid and cost effective review.

WADA-accredited Laboratories are also highly experienced with quality assurance programs. By centring APMUs around *WADA*-accredited Laboratories, *ADOs* are relieved of the need to undergo APMU approval and to demonstrate the qualifications of APMU staff.

5. Who will be affected by the changes brought about by the implementation of the TD2019APMU?

Any organization currently hosting an APMU will be affected by the changes proposed in TD2019APMU. This includes the 11 Laboratory-associated APMUs, the 6 *ADOs* running compliant *ABP* programs using internal APMUs, and the remaining *ADOs* with internal APMU accounts in *ADAMS* who are not managing Passports according to

Annex L of the ISTI (the majority of whom do not yet have an *ABP* program or dedicated internal APMU staff).

Any *ADO* currently using the services of a *WADA*-accredited Laboratory-associated APMU will not be affected by the implementation of the TDAPMU. This includes the 54 *NADOs* and the 52 *IFs* currently working with Laboratory-associated APMUs.

Thus, only about 5% of functional *ABP* programs will be affected. *ADOs* will maintain the ability to view *ABP* data and APMU reports in *ADAMS* in a non-anonymous manner to integrate with other sources of information about athletes to facilitate intelligence-led testing and investigations.

6. Why is independence important at the APMU level? Don't the external ABP Experts provide adequate independence?

ABP Experts reviewing Passports in *ADAMS* provide independent, scientific evaluation of Passports for result management decisions taken by *ADOs* and disciplinary panels. This expert testimony serves as evidence of doping that can lead to an anti-doping rule violation (ADRV). This role differs from that of an APMU, which has a role in Passport management and providing testing recommendations.

While the independence of Experts is critical for the advancement of *ABP* cases by providing expert testimony that is objective, the APMU also takes decisions where objectivity is advantageous. For example, the decision to order a specific analytical test should not be influenced by knowledge of the *ADO's* administrative considerations (e.g., budget). Similarly, the APMU evaluation of a Passport or the decision to send a Passport for review should not be influenced by knowledge of the *Athlete's* identity. The centring of APMUs around *WADA*-accredited Laboratories brings an important layer of independence to the Passport management process.

7. Why are *ADO* employees allowed to act as APMU managers for APMUs hosted in *WADA*-accredited Laboratories?

Recognizing that APMU expertise exists in some *ADOs*, flexibility was added to the recent version of the TDAPMU in order to allow the possibility for these APMU managers to work within the framework of a Laboratory-associated APMU. The passport management activities of external APMU managers will fall under the responsibility of the APMU director (who remains part of the *WADA*-accredited Laboratory), and as such will have oversight from the APMU in terms of quality assurance. The performance of these APMU managers will also directly impact the approval process of the APMU, so these are viewed as exceptional cases where the APMU director, after reviewing the qualifications of the APMU manager, will contract

the *ADO*-associated APMU manager. These APMU managers must still carry out all APMU operations in an anonymous manner, using specific Laboratory-associated APMU ADAMS account.

In the rare case where the APMU manager is part of an *ADO*, it is assumed that the identity of particular Passports under the custody of their *ADO* may be known to them because this APMU manager may have access to *ADAMS* via a non-anonymous *ADO ADAMS* account. In these cases, the APMU manager will have ready access to additional information to inform testing recommendations.

8. Can an APMU manager at an *ADO* manage Passports for other *ADOs*?

Yes, a qualified APMU manager who is located in an *ADO* may also manage Passports on behalf of other Passport Custodians, provided the APMU is approved by *WADA* and centred around a *WADA*-accredited Laboratory.

9. Are *ADOs* encouraged to build scientific and *ABP*-specific expertise?

While this document formalizes the APMU role around the scientific expertise of *WADA*-accredited Laboratories, it does not address, or preclude, the need for scientific expertise within *ADOs* for other purposes, including *Target Testing*, investigations and results management. The ability of a testing manager to integrate *ABP* data with other *Athlete* information in order to direct *Target Testing* clearly benefits from scientific knowledge of the doping substances and methods as well as the physiological response to doping.

In addition to scientific expertise, *ADOs* are encouraged to continue to build internal capacity to implement effective *ABP* programs. For example, *WADA* will continue to support educational symposia to promote the exchange of knowledge and harmonization of practice related to various facets of *ABP* programs including testing, legal issues, and investigations

10. Why is a minimum level of Passports/APMU Reports specified as part of the APMU approval process?

Similar to other skillsets, APMU quality correlates with experience. Exposure to a significant number of Passports increases experience, in particular with unique cases, and insures efficient and effective Passport management. To date, many issues observed with APMU quality were observed in APMUs with low Passport numbers. This requirement aims to insure a minimum level of experience, and hence quality, across all APMUs.

11. Can an APMU be hosted in a WADA-approved laboratory for the ABP?

No. WADA-approved laboratories for the ABP perform only *ABP* blood sample analysis, often within a clinical setting, and as such do not necessarily have specific anti-doping expertise such as knowledge of steroid analysis.

12. Why should “normal” Passports be reviewed?

Passports that are not flagged as atypical by the Adaptive Model in *ADAMS* can be sent to an Expert for review at any time. Such a review may be triggered by additional elements not considered by the Adaptive Model, by abnormal levels or variations of markers, or other non-analytical evidence in relation to the *Athlete* concerned. In addition, it is important for Experts to be exposed to normal Passports on a regular basis to avoid biases in interpretation and analysis of profiles.

APMU Reports from normal Passports will be included in the number of APMU Reports per year considered necessary to maintain APMU approval.

13. Why is it necessary to have an *ABP* panel of Experts from more than one country and institution?

This diversity is required in order to promote independence in the initial reviews, reduce potential for conflicts of interest, and ensure a balance of opinions.

14. Why is it necessary to have an *ABP* panel of Experts that includes one Expert with experience on a WADA-approved APMU?

In addition to promoting transfer of knowledge and experience, this requirement aims to ensure a minimum level of experience on a given Expert panel, should a given Passport advance towards an *ADRV*. As an *ABP* case advances, an experienced Expert provides an advanced understanding of forensic reasoning and logic in the evaluation of evidence, experience reviewing *Athlete* explanations and writing joint Expert opinions, and confidence in presenting expert opinions in court. The number of these experienced Experts continues to increase and diversify as the number of *WADA*-approved APMUs and their Expert pools grow. Thus, this requirement is not viewed as being restrictive in terms of the development of new Experts. On the contrary, this requirement helps strikes a balance between promoting the development of new Experts and ensuring an experienced review of Passports.

15. How will WADA provide Expert/APMU education? How will APMUs ensure that Experts receive it?

WADA's anti-doping eLearning platform (ADeL) hosts an *ABP Expert* Guide, which is an educational reference course exclusively for designated *ABP Experts*. Currently, only those Experts who are engaged by an APMU to review Passports will be provided access. APMU staff will be provided access after their APMU is approved by WADA.

16. What type of *ADAMS* account will be used by an APMU manager located at an *ADO*?

All APMU managers, regardless of physical location, will be required to use a Laboratory haematological APMU user or steroidal APMU user account in order to perform APMU activities in *ADAMS*. If the same individual also performs other tasks for an *ADO*, such as *Testing* planning, they will login into *ADAMS* using a different user account that provides the necessary *Athlete* information

17. What is the timeline for the entry into force of the APMU approval process?

Applications for WADA APMU approval will be considered beginning on the effective date of the TD2019APMU, though expressions of interest and preliminary discussions are welcome at any time. In 2019, *ADOs* should ensure that the APMU with which they work has applied for and obtained WADA approval and that Experts who review Passports under their custody meet the requirements of the TD2019APMU.

Existing APMUs should prepare to apply for and obtain approval prior to 1 January 2020, as passport management by an approved APMU will be mandatory on this date. For existing APMUs, applications are expected to be facilitated by reporting from *ADAMS* of numbers of APMU reports and numbers of haematological and steroidal passports that are currently managed.

18. Is it mandatory to follow APMU recommendations?

While an *ADO* should make all efforts to implement APMU recommendations, it is acknowledged that there are specific situations where this is not possible. In addition, the *ADO* may have additional information not available to the APMU (e.g., competition schedule, specific intelligence) which may change the context of the APMU's recommendations. In all cases, the *ADO* should keep record of why the APMU recommendations were not followed.

19. Why is it recommended to have one manager per module of the *ABP*?

Because each module has its own specificities, they require a different expertise in order to manage. Thus, in an ideal *ABP* program, each module should be managed by a different individual with qualifications specific to that module.

20. Why can a lab-associated APMU act as first expert for the steroid module but not the haematological module?

WADA-accredited labs are world experts in urine steroid analysis and profiling. The majority of the published research examining the effects of steroids on the urinary steroid profile is carried out in *WADA*-accredited labs. In addition, steroidal ATPFs can sometimes be related to analytical factors (e.g., secondary markers close to the limit of quantification, alcohol, incomplete hydrolysis, bacterial contamination) and laboratory scientists are thus well positioned to evaluate the results and rapidly recommend additional analytical tests or sample collection, as appropriate. As such, the qualified personnel of these labs have the ability to act as a first Expert for the steroid module of the *ABP*.

With regard to blood doping expertise, a much smaller percentage of *WADA*-accredited laboratories carry out and publish research into the effects of blood doping on the *ABP*, thus it is less common to find qualified haematological Experts in a laboratory (see Question 22 below). On the other hand, the labs have strong expertise in blood analysis and are well positioned for the management of blood sample validity in the role of APMU. In rare instances where appropriate blood doping expertise is found associated with a lab, this individual may act as an *ABP* Expert for the haematological module for other APMUs.

21. How is the first Expert chosen from a panel of Experts for a given ATPF?

When sending a Passport for review, the APMU chooses the Expert most suited to the abnormalities present in the passports. For example, if there is an ATPF for elevated HGB, which may be related to changes in plasma volume, the APMU should send the passport to the Expert with the most experience in plasma volume shifts. Similarly, if the Passport presents elements suggesting a pathology, it should be preferentially sent to the haematologist on the Expert panel.

22. What is a qualified Expert?

ABP Experts provide independent, scientific evaluation of biological variables in passports in view of possible causes – a critical and central aspect of the *ABP*. This passport evaluation provides a scientific basis for decisions taken by *ADOs* and

disciplinary panels and thus has a significant impact on anti-doping proceedings. Both the qualifications of the expert and the review itself should therefore comply with the standards for the evaluation of scientific evidence in forensics [1]. *ABP Experts* require documented knowledge and experience in the concerned field such that they are qualified to provide an expert evaluation of a passport and expert scientific testimony in anti-doping proceedings.

1. Schumacher YO, D'Onofrio G. Scientific expertise and the Athlete Biological Passport: 3 years of experience. *Clinical Chemistry* 2012;58:979–85. <https://doi.org/10.1373/clinchem.2012.183061>.