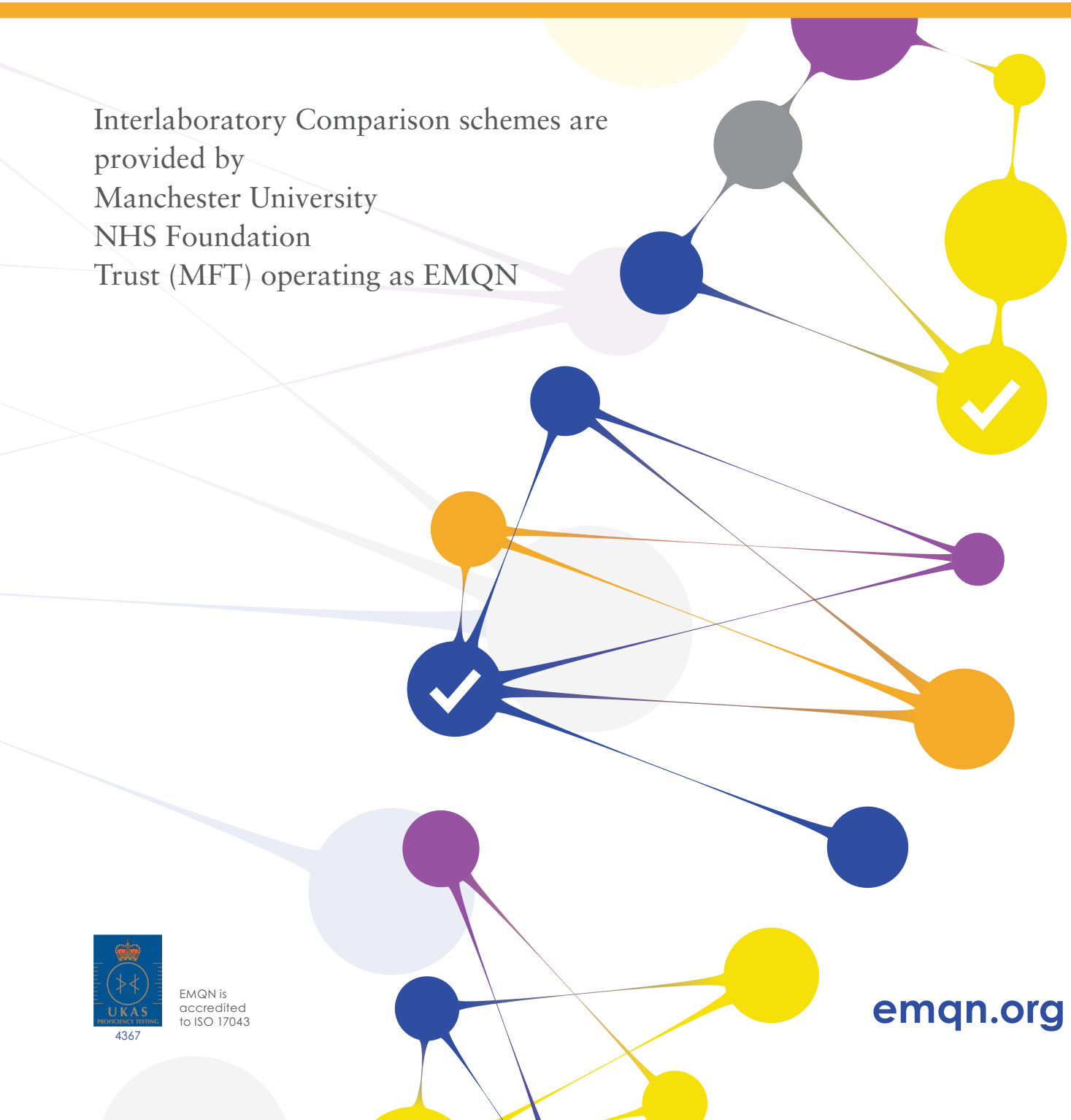
EMQN

The European Molecular Genetics Quality Network

Interlaboratory Comparisons (sample exchanges): Guidance for EMQN Laboratories

Interlaboratory Comparison schemes are provided by Manchester University NHS Foundation Trust (MFT) operating as EMQN



UKAS PROFICIENCY TESTING 4367

EMQN is accredited to ISO 17043

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Introduction

Laboratory accreditation standards (for example ISO 17025, ISO15189) mandate that laboratories should participate in EQA schemes (where they exist). If no EQA scheme is available, then the standards require laboratories to participate in interlaboratory comparisons or sample exchanges.

Interlaboratory comparisons (or sample exchanges) between laboratories are a method of monitoring laboratory performance which are suitable for accreditation purposes in certain defined circumstances, for example tests on very rare diseases where there are a small number of labs perform testing, and there are no EQA schemes available. EMQN will provide support for Interlaboratory Comparisons (ILCs) in accordance with **EA-4/21 INF: 2018 Guidelines for the assessment of the appropriateness of small interlaboratory comparisons (ILC) within the process of laboratory accreditation.**

The benefits for your lab in joining an ILC mediated by EMQN are:

- EMQN has links with a large network of laboratories who may also be interested in joining an ILC,
- EMQN already plans and delivers external quality assessment (EQA) to the standards described in ISO17043,
- EMQN as the ILC organizer can give independence of assessment to all participants in the scheme,
- EMQN can provide a certificate as evidence of participation for accreditation, and
- EMQN will act as an independent intermediary to help resolve any discordant results.

EMQN will facilitate the exchange of materials between laboratories for the ILC, will assess the genotyping results, and will provide a report summarising the results for the ILC.

ILC Proposals and registration

Please submit an **Expression of interest form** if you would like to propose an interlaboratory comparison study. EMQN will accept a minimum of 3, and a maximum of 7 laboratories for an ILC study. Once sufficient participants register interest, EMQN will contact you to arrange registration. **All ILC studies will be genotyping-only – no assessment of clinical interpretation will be made.**

Cost of particpation

There is an annual fee of £200 to participate per ILC study, and EMQN membership will be required. Participating laboratories will be asked to commit for a minimum of 3 years (total cost of £600).

Samples

Participating laboratories will contribute DNA samples from clinical cases to EMQN for the ILC study, along with information related to your laboratories' accreditation and the methods used to test the samples.

EMQN will perform basic QC of the DNA sample (to assess the amount of dsDNA and DNA quality), anonymise the materials, and co-ordinate distribution to participating laboratories with matching clinical referral information.

All participanting laboratories will be asked to send between 2 or 3 samples for testing over the 3 year period. EMQN will request sufficient DNA to provide approximately 2 µg per participant (8-16µg per sample; see table on page 3 for estimations of the amount of DNA to be provided). The actual amount of DNA required will be specific for each particular disease; if there is sufficient material, the same samples will be sent to all participants in the

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interlaboratory comparison study. If this is not possible, sample exchanges will be co-ordinated between smaller groups of laboratories. Please note that if samples are distributed to all participants, you will test at least one of your own samples (anonymised) during the 3 year period.

Number participating labs	Minimum number samples to be provided by each participant over 3 years	Minimum quantity of DNA (ug) per sample to provide DNA to all participants (2 ug per particpant[1])
3	3	8 µg
4	3	10 µg
5	2	12 µg
6	2	14 µg
7	2	16 µg

[1] An additional 2ug of DNA is requested for EMQN quality control of each material, and in the event of need for independent sample validation (if required).

Timelines and instructions

EMQN will provide a handbook for participants with more detailed guidance about our ILC studies.

We will notify laboratories of the timelines for the ILC study; each round will be scheduled to take place within a calendar year.

Results submission

Results will be submitted to EMQN via an online form. Participants will be asked to include the mock patient identifiers, the sample genotype with basic classification of pathogenicity (eg. class 5 pathogenic, class 4 likely pathogenic, class 3 UV), and the relevant reference sequences.

Assessment and certificates

There will be NO poor performance criteria applied to ILC studies. The results will be evaluated by EMQN for accuracy of patient identifiers, as well as the genotype and classification of pathogenicity, which will be assessed in comparison to the consensus result amongst the participating laboratories.

If the consensus results are discordant, EMQN will mediate discussions to resolve the discrepant results. If necessary, EMQN can send a sample for validation by NGS, and an additional fee will be charged to each participating labs to cover the costs of independent sample validation.

A summary report on the results of the ILC study, as well as your individual scores will be issued after the completion of the assessment period and these documents will be available via your EMQN website account.

A certificate of participation will be available following completion of the appeals process, shortly after the final results have been released to the laboratories.

Further information

If you have any questions, and would like to discuss ILC studies further, please contact the EMQN team at office@emqn.org.

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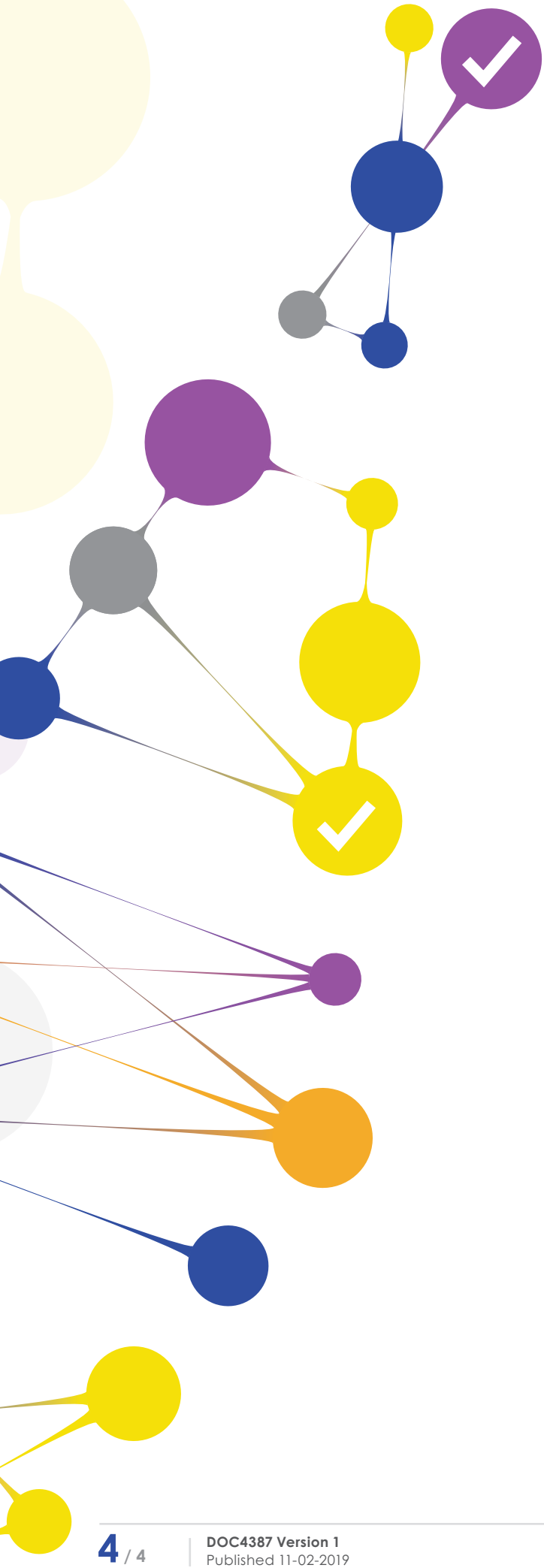

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